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Submitted in fulfilment of the requirements for the degree of Doctor of Philosophy by publication

Faculty of Health, School of Nursing
Institute of Health and Biomedical Innovation
Queensland University of Technology

A randomised controlled trial evaluating outcomes of emergency nurse practitioner service

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Associate Supervisors: Dr Sonya Osborne

External Associate Supervisor: Dr Gerard O'Reilly

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Keywords

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Under Review

1. **Timely analgesia by Nurse Practitioners - an audit**

Oral paper.

Natasha Jennings, Gerard O'Reilly, Arushi Kansal, BiswaDev Mitra, Glenn Gardner.

12th International Conference for Emergency Nurses, Perth, October 2014.

2. Developing a theoretical framework to evaluate health services research

Rapid Communication Poster Session.

Natasha Jennings, Sonya Osborne, Glenn Gardner.

9th Conference of the Australian College Nurse Practitioners, September 2014.

3. Designing a RCT evaluating emergency nurse practitioners services

Oral paper.

Natasha Jennings, Gerard O'Reilly, Glenn Gardner.

5th Australian Symposium of Emergency Nurse Practitioners, Sydney, May 2014.

4. Why we need pragmatic nursing research

Oral paper

Natasha Jennings.

Alfred Nursing research forum, October 2013.

5. Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective analysis

Oral paper

Natasha Jennings, Emma McKeown, Gerard O'Reilly, Glenn Gardner.

ED NURSEPRAC 2013, Australian College of Nurse Practitioner Conference, Melbourne, May 2013.

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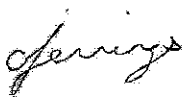
(Student Author's name) Natasha Jennings	I mentored the authorship team and lead the study design, search strategy, analysis and lengthy journal peer review process. I engaged all team members. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship that includes: substantial contribution to the conception of the review; the acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published.
Signature 	
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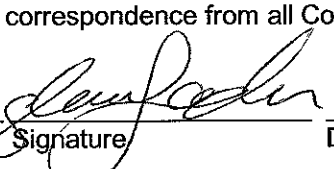
GLENN GARDNER  4/5/15

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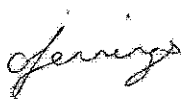
Signature 	
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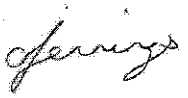
(Student Author's name) Natasha Jennings Signature  Date 23/01/2015	In collaboration with the team I was responsible for the initial concept of the RCT design with ethical and governance clearance managed by myself. In collaboration with Gerard, I was responsible for the statistical analysis. I was responsible for initial drafting and redrafting of the manuscript drafts and coordinating the author team critiques.
Co-author's name* Gerard O'Reilly, Biswadev Mitra, Glenn Gardner.	All authors contributed to the original concept and study design. GO conducted all the statistical analyses with NJ and BM. NJ, BM and GO interpreted the results and prepared the manuscript. GG provided the final critique of the manuscript and supervised the conduction of the trial.
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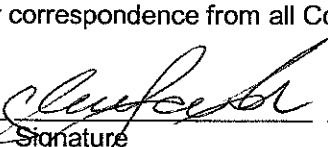
GLENN GARDNER  4/5/15

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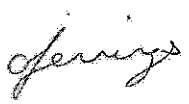
Signature 	
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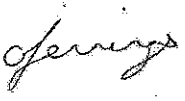
Signature 	
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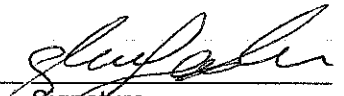
GLENN GARDNER  4/5/15

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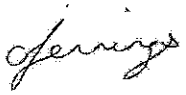
Signature 	
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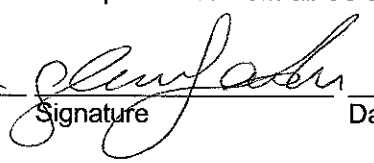
GLENN GARDNER  4/5/15

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   Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective analysis.

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

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Signed…… ……..

Dated……Friday 17th April 2015……..

Acknowledgements

Before l commence my acknowledgments l wanted to document the beginning of my PhD journey, starting back in January 2011. I had previously dabbled in some outcomes research related to emergency nurse practitioners and certainly had developed a keen eye on the existing literature and the promotion the role. I brainstormed my ideas and put together a research proposal. I engaged many of my colleagues from the Alfred Emergency and Trauma Centre about my proposal and l started investigating options of how l could study physically, emotionally and financially. I had two small children under three and my husband, also working in emergency services which entailed, travel, shift work and long hours. I sent an email to another university where l had undertaken my Master's degree and did not receive any inspiring feedback or support for an application for a PhD candidate position. After hearing Professor Glenn Gardner present at a healthcare symposium in Melbourne, l realised l needed to be exposed to her expertise and ground-breaking nurse practitioner research.

13 October 2011. I composed a short email detailing my proposal and current clinical role to Professor Glenn Gardner. Glenn's response was "timing of your interest is very good- tell me about your academic background". I responded with a follow up email, detailing my publication profile and waited for her response. She said she was, "loaded up with PhD students at present but had two nearing completion in January, had l tried some local universities". She proceeded to suggest some suitable potential supervisors. I replied to her email with my preliminary proposal and my interest to have her as a principal supervisor. She replied saying, "she was very happy l was going to be looking at clinical patient outcome research – and she thought l was brave to start this with two small children – she had been there and knows the challenges."

01 December 2012. I sent in my application for my PhD candidature. This is where the official journey starts.

Firstly, l would like to thank my principal supervisor, Professor Glenn Gardner. Her enormous professional support and advice has provided me with great opportunity for development throughout my candidature. She has inspired me to have grand visions about my future aspirations and l will always be grateful l started this journey being mentored and fostered by her. Secondly, l would like to thank my external supervisor and colleague Dr Gerard O'Reilly, who despite wearing several professional hats, which takes him to foreign lands with the World Health Organisation and other humanitarian efforts, his unwavering support with the statistical analysis and on the ground support, has been enormous. My associate supervisor, Dr Sonja Osborne has provided critical academic input into this thesis and has been always available for support. My darling husband Paul, my two children Amelia now six and Cooper five, l love you all the way to the moon and back and more. Paul has been a calming influence when things were very challenging and has always been there to say it will be okay. It has been challenging juggling a PhD candidature, working clinically enough to pay the bills, being a wife and a mother. But it has been so rewarding. I have shown hard work pays off and l am so proud of my achievements. A special thank you to my in-law family: Fran, Sue and Chris for extra babysitting and my best friends Murray and Kerry. Thankyou to Nana and Pa for the extra weekends of babysitting and your support.

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Abstract

Background

Advanced practice nursing roles such as the emergency nurse practitioner (E-NP), were developed as an innovative and cost effective approach to meet increasing patient demand for service and the changing needs of the healthcare consumer population. The rapid uptake of nurse practitioner (NP) service in Australia has outpaced evaluation of this service model. Effectiveness of E-NP service has not been evaluated previously, in relation to safety and quality of patient clinical outcomes. Emergency nurse practitioner service is framed in this study as a complex systems intervention and required a unique framework within health services research to guide the evaluation approach.

Aims

The aim of this research was to evaluate E-NP service effectiveness on clinical indicators related to quality of patient care and service responsiveness and to contribute an evidence base for future policy and health service planning. Hence the following null hypotheses were tested:

> For patients presenting to the Emergency Department (ED) with pain, allocated to the fast track zone and who receive care from either an E-NP or standard care, there will be no difference in pain score reduction and time to analgesia. Secondary outcomes evaluated included waiting time, number of patients who left without being seen, length of stay in the ED, representations with 48 hours, pain score documentation and the utilisation of evidenced based guidelines.

Methods

A pragmatic randomised controlled trial was conducted to compare the effectiveness of nurse practitioner service versus standard medical care in the ED of a major referral hospital in Australia. Patients presenting with pain were randomly assigned to receive either standard ED

medical care or NP care. Primary investigators were blinded to treatment allocation for data analyses. The primary outcome measure was the proportion of patients receiving analgesia within 30 minutes from being seen by care group. Secondary outcome measures included comparative results for time to analgesia from presentation, documentation and changes in pain scores, waiting time, number of patients, who left without being seen, length of stay in the ED, representations with 48 hours, pain score documentation, utility of evidenced based guidelines.

Results

There were 260 patients randomised, with 128 receiving standard ED medical led care and 130 receiving NP led care. The proportion of patients who received analgesia within 30 minutes from being seen was 49.2 % (n=64) in the NP group and 29.7% (n=38) in the standard group, a difference of 19.5% (95% CI: 7.9-31.2%, p=0.001). Of 165 patients who received analgesia, 64 patients (84.2%) received analgesia within 30 minutes in the NP group compared to 38 patients (42.7%) in the standard care group, a difference in proportion of 41.5% (95% CI: 28.3-54.7%, p <0.001. Mean time from being seen to analgesia was 25.4 (SD 39.2) minutes for NP care and 43.0 (SD 35.5) minutes for standard care, a difference of 17.6 minutes (95% CI: 6.1-29.1, p=0.003). There was a difference in the median change in pain score of 0.5 between care groups but this was not statistically significant (p=0.13). There were no significant differences between the two groups in regards to waiting times, length of stay, numbers of patients who did not wait, patient representations within 48 hours and the utility of evidence based guidelines.

Conclusion

Emergency nurse practitioner service effectiveness was demonstrated through superior performance in delivery of timely analgesia for ED patients. The impact of E- NP effectiveness on key service indicators demonstrated equivalence with standard ED care. This result validates NP service in being able to demonstrate comparable outcomes and provide a much-needed evidence base that NP service is an integral part of the changing health system reform and service innovation.

Chapter 1. Introduction

1.1 The changing Australian healthcare landscape

The contemporary Australian healthcare landscape is burdened with the growing incidence of chronic diseases in the community, reduced access for patients to primary healthcare and reductions in health care expenditure. These factors, coupled with rising healthcare costs and consumer demand for timely and efficient patient care have all contributed to increased demands upon the healthcare system (Council of Australian Governments, 2011, Australian College of Emergency Medicine, 2009).

Innovative efficient workforce planning requires ongoing assessment and matching to population needs (Australasian Health Workforce Association, 2012). Delivering outcomes to meet population needs requires healthcare directors, policy makers and clinicians to demonstrate leadership to reform our current health services. Healthcare reform requires these stakeholders to explore and create a workforce model that is reflexive and future oriented.

1.2 Innovative nursing models

The National Health Workforce Strategic Framework examined methods to address structural pressures on the health system to better meet changing health care needs of the population. The framework identified a clear requirement to develop new and innovative models of care for health care service delivery recognising that:

- existing professional roles may need to evolve
- opportunities exist to explore the flexibility of the workforce, including innovative approaches to skill mix, new workforce roles, and changes to scope of practice (Australian Health Ministers Conference, 2004).

The nursing workforce has developed and implemented many innovative models of care that promote the concept of healthcare reform. One model of care offering flexibility and adaptation to the changing needs of the landscape is the nurse practitioner (NP). Nurse practitioners have been introduced as a service innovation model in response to the changing healthcare landscape.

The honourable Nicola Roxan, former federal Health Minister in her opening address to the Australian Nurse Practitioner Conference 2010, affirmed that NPs play a vital role in delivering quality healthcare to all Australians (Roxan, 2010). Ms Roxan referenced NPs as part of the government reform agenda to deliver access to essential frontline services in primary care. Ms Roxan also reported that NPs have the opportunity to deliver innovative service models tailored to meet these target population needs.

The NP as an innovation model embodies traditional professional identities and autonomous practice boundaries to deliver healthcare. The nature of NP work involves a hybrid model of care delivery, which includes a combination of nursing care, diagnostic activities, intervention-based treatments and the use of medicines. Some of these activities have traditionally been limited to the scope of medical practice (Gardner et al., 2010). The NP service model delivery establishes improved access, efficiency and quality of patient care as key performance measures to achieve healthcare reform (Rother and Lavizzo-Mourey, 2009, Wilson et al., 2008).

These innovations have led to recurrent confusion over the NP role, responsibility, accountability, scope of clinical practice, professional boundaries and effectiveness (Department of Health Queensland, 2012). The impact of the NP role on health service delivery needs to be supported by research and evidence to inform healthcare policy and service developments.

1.3 Emergency Department service issues

Health service areas currently under pressure for reform in Australia are hospital emergency departments. Emergency departments (ED) have seen more than 37% growth in patient presentations over the last decade and this has contributed to an ever-growing burden on the delivery of quality patient care (Lowthian and Cameron, 2012). The capacity of EDs to consistently deliver timely, high quality patient care is impacted by the increase in the number and complexity of presentations. Emergency department overcrowding, access block, the growing burden of chronic diseases in the community, reduced access to primary healthcare have all contributed to increased demand in ED services (Health Workforce Australia, 2012, Sprivulis et al., 2006, Lowthian et al., 2011). Emergency department overcrowding is seen as the greatest single impediment to safe and efficient ED services in Australia and New Zealand (Cameron et al., 2009) significantly resulting in increasing waiting times, adverse events, mortality and hospital length of stay.

Waiting times, adverse events, mortality and hospital length of stay form part of a set of clinical indicators of health service delivery. These defined national clinical indicators are compiled by the Australian Council of Healthcare Standards (ACHS) annually to provide clinical perspectives of trends in service and how to improve quality and safety of care for patients. The ED national clinical indicators are government mandated and designed to transparently monitor, analyze and evaluate a health service's performance (Department of Health Victoria, 2012). Increased ED services demand has resulted in the clinical quality indicators of waiting times, length of stay, time to analgesia and mortality becoming adversely affected and impacting effectiveness of quality patient care (Lowthian and Cameron, 2012). These indicators are the current benchmarks utilised by healthcare directors, policy makers and clinicians to measure quality of patient care in the ED.

The major recommendation from the Australian Health Workforce Advisory Committee's evaluation of ED models of care was the need to address these service issues in the ED with innovative models and workforce reform. The developments of innovative models of care and lean thinking have been strategies to address some of these issues. The implementation of the

emergency nurse practitioner service is part of a reformative model of health service that has the potential to directly impact service outcomes and quality of patient care.

1.4 The emerging emergency nurse practitioner service

Increasing service pressures in the ED have resulted in the adoption of service innovation models; the most common and rapidly expanding of these is the emergency nurse practitioner (E-NP). The E-NP model is the fastest growing NP model nationally with a 61% increase in the last three years (Middleton et al., 2011). Emergency nurse practitioners have been viewed as one potential solution to address the increased demand and overcrowding in the ED and have been employed to improve service indicators such as access and efficiency, directly impacting quality patient care (Wilson et al., 2009, O'Connell and Gardner, 2012).

The E-NP role is a new paradigm in health care service delivery designed to improve timely, quality care for patients. The E-NP role includes assessment and management of clients using critical decision-making skills, referring directly to medical and other health care providers, prescribing medications and ordering and interpreting diagnostic tests.

The rapid uptake of E-NP service in Australia has outpaced the capacity to evaluate this service model in terms of outcomes related to safety and quality of patient care. There are significant gaps in the research evaluating the impact of E-NP service on the outcomes and processes of patient care and service responsiveness.

The studies reported in this thesis examined the impact of E-NP service on key patient care and service indictors. It provides a much needed evidence base for NP service innovation at a level that has not been studied before. Furthermore, health services research frequently struggles to establish an inquiry that is sufficiently flexible to examine service level interventions using a randomised controlled trial (RCT) approach (Hawe et al., 2004, Black, 1996). This research met this challenge and conducted a RCT in the ED environment with a stable E-NP service intervention.

1.5 Research aim

The aim of this research was to evaluate E-NP service effectiveness on clinical indicators related to quality of patient care and service responsiveness and contribute an evidence base for future policy and health service planning. Hence the following null hypotheses were tested:

For patients presenting to the ED with pain, allocated to the fast track zone and who receive care from either an E-NP or standard care, there will be no difference in:

Primary outcomes

Pain score reduction and time to analgesia

Secondary outcomes

Service indicators of:
Waiting time
Number of patients who left without being seen
Length of stay in the ED
Representations with 48 hours
Pain score documentation
Utility of evidenced based guidelines

This thesis by publication is a collection of activities targeted to conducting the most robust and definitive pragmatic RCT to evaluate E-NP service effectiveness on quality patient care and service responsiveness.

A series of questions used to guide this study were:

1. What is the current evidence surrounding E-NP service effectiveness in relation to safety and quality of patient care outcomes?
2. What is the current clinical profile of E-NP service at the intended study site?
3. How do you develop a health services research trial using a pragmatic approach?

4. What is the effectiveness of E-NPs on service and quality of patient care indicators, with that of standard care in the ED.

1.6 Thesis outline

This thesis is a body of original work developed and presented in six manuscripts; four of which are published, one accepted for publication in December 2014 and one manuscript currently under peer review. Each of these publications and manuscripts inform subsequent work and is anticipated to contribute to new knowledge in the emerging discipline of nurse practitioners and health services research. The thesis presents the approach and rationale utilised to achieve the research aims to conduct a pragmatic randomised controlled trial.

Chapter 2 is a literature review examining E-NP effectiveness on patients and service outcomes. The central work of Chapter two is a systematic review that appraises extant evidence on E-NP service titled: ***The impact of nurse practitioner services on cost, quality of care, satisfaction and waiting times in the emergency department - a systematic review.*** The findings from this first published manuscript were used to guide and communicate the existing knowledge of E-NP effectiveness and identified the lack of high quality research in this field. The work in this chapter informed and supports the subsequent research activity.

Chapter 3 reports the preparatory work required for the main research and is framed around two studies that provided essential information and metrics to inform the subsequent research design. The first of these was an audit of E-NP patients titled: ***Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective analysis.*** This published article achieved several goals for design of the main study. It describes the E-NP service profile in the ED setting, established the feasibility of the study and informed selection of a sampling frame for patient recruitment. The aim of this audit was to establish baseline characteristics of the E-NP cohort for patients at which to proceed to inform the next stage of the research activity. The second published article, ***Time to analgesia for care delivered by nurse practitioners in the***

emergency department, reported the pilot study that tested data collection processes and informed the sample size and outcome measures for the RCT.

Chapter 4, the conceptual framework for the RCT describes the relationship between E-NPs, their context and outcomes. The development of an appropriate methodology that accommodates the intricacy and methodological challenges of evaluating complex interventions is detailed. This chapter develops the conceptual framework required to guide the pragmatic RCT to evaluate E-NP service effectiveness and to report the findings.

Chapter 5 is the main research methods and describes the research design for the pragmatic RCT. This is reported in a publication titled: ***A protocol for a pragmatic randomized controlled trial evaluating outcomes of emergency nurse practitioner service.*** The systematic review (Chapter 2) showed that a study of this nature had not previously been conducted. The impetus for this publication therefore was to submit the intended study design to a high profile nursing journal for peer review of the research approach. An additional goal was to disseminate information about the current study to the discipline.

Chapter 6 reports the results of the pragmatic RCT that evaluated clinical and service outcomes of E-NP service. Reporting of these results was guided by the health service research framework for complex interventions, that evaluated the E-NP service intervention at i) the patient level and ii) the service level. The core of this chapter therefore is two publications. The first reports E-NP service effectiveness at the patient level and is titled: ***The effectiveness of emergency nurse practitioner service on timely management of analgesia: A pragmatic randomised control trial.*** This manuscript is currently under peer review. The second manuscript reports findings of the evaluation of E-NP service effectiveness at the service level and is titled: ***The effectiveness of emergency nurse practitioners on service indicators in the emergency department: A pragmatic randomised control trial.*** This paper is also currently under peer review.

Chapter 7 is the discussion on the overall findings of the research connecting the individual chapters of the research activities to present a body of work focused on the emerging discipline of nurse practitioner health services research. This chapter also details recommendations based on the research findings and subsequent future research opportunities

Chapter 2. Literature Review

2.1 Introduction

The rapid uptake of E-NP service in Australia has outpaced the capacity to evaluate this service model in terms of outcomes related to safety and quality of patient care. With increasing patient demands for service, and health care reform high on government agendas, the provision of quality patient care and health service performance needs to be addressed. This discussion will focus on development of E-NP roles from both a local and international context, briefly describe some of the issues relating to delivering ED services and review the national and international evidence relating to the effectiveness of E-NP on service outcomes and quality of patient care.

2.2 Summary of E- NP role development

The NP role was first established in the United States of America (USA) in 1967 as a substitute for primary care physicians (Silver et al., 1967) in under-serviced areas. As a result of lack of primary care access for patients, nurses expanded their scope of practice to meet the needs of the population and developed educational programs that provided comprehensive care to children. This university program was accredited with graduating the first paediatric NPs (Ridgway, 2012) internationally. Nurse practitioners now work in a myriad of settings providing care across primary, secondary and tertiary contexts (American Academy of Nurse Practitioners, 2010). As the NP role has developed, service capacity in sub speciality areas such as emergency, cardiovascular, endocrinology and oncology has been enriched in healthcare settings. Latest figures from 2010 estimate there are over 155,000 licensed NPs across the USA (American Association of Nurse Practitioners, 2011).

Canada followed the USA NP movement with the implementation of NPs in the 1970's. The Canadian NPs were firstly accredited to work in remote stations around the rural landscapes of Nova Scotia (Health Canada, 2007) delivering primary care. In 2010, over 3,000 NPs worked in the healthcare system within a variety of settings where the population demand for services is a

driver for reform. Canadian NPs are seen to provide an integral function in delivering high quality primary patient care (Canadian Nurse Practitioner Initiative, 2011).

The United Kingdom NP roles were firstly developed for similar needs of the population to that of the USA; that is working in primary care settings and filling gaps in medical services (Nursing, 2012). The first acknowledged E-NP was introduced in Essex in 1988 (Cooper et al., 2002). The role was introduced as a response to patient complaints about quality of care and waiting times for services. A large body of descriptive research has emerged from the UK since development of the NP role concentrating on outcomes related to waiting times, length of stay, patient satisfaction, cost effectiveness and re-presentation (Wilson et al., 2009).

Australia first implemented the NP role in New South Wales (NSW) with a pilot project in 1995 (Currie et al., 2007, Middleton et al., 2011). The pilot explored sustainability, scope of practice and health outcomes resulting in legislative changes to support such a role. In 2000 the first NP was authorised in a primary care setting. In March 2014, the Nursing and Midwifery Board of Australia (NMBA) reported that the number of NPs across Australia totalled 1087 (Nursing and Midwifery Board Australia, 2014a).

The subspecialty role of the E-NP has emerged as a response to an overstretched healthcare system where demand for services has outweighed capacity for access to care. The E-NP subspecialty has had a 60% increase over the last three year period, (Middleton et al., 2011). In the 2009 NP census just over 30% of all NP's in Australia identified their specialty as emergency. The current national figure for E-NPs is approximately 250 (Nursing and Midwifery Board Australia, 2014b).

2.3 Emergency Department Services issues

Over the last decade, EDs have had rapidly increasing healthcare demands. Difficulties accessing primary healthcare in the community, growth in the number of patient presentations and an

ageing population are some of the complex contributors to these demands (Sykes et al., 2012). Emergency department service issues include increased waiting times, ED overcrowding, increased length of stay and poor patient outcomes reported both nationally and internationally that are associated with the inability to achieve quality of patient care. Internationally, an Institute of Medicine Report (Institute of Medicine, 2009) discussed six domains of quality of care that included safety, patient centeredness, timeliness, efficiency, effectiveness and equity. Quality of care and service indicators are a measure to assess access, timeliness, safety, efficiency and patient centred care (Lowthian and Cameron, 2012). These parameters are now the key focus of ED service performance targets implemented by the Australian government (Emergency Care Institute New South Wales, 2013).

2.4 Review of research into E-NP service

A review of the international literature located four early-randomised control trials (RCTs) conducted to investigate the NP role in the ED setting between 1994 and 2002. Pioneer nurse practitioner researchers (Powers et al., 1984, Sakr et al., 1999, Cooper et al., 2002, Chang et al., 1999) conducted their studies in the USA, UK and in Australia. All four RCTs compared E-NPs with traditional models of care. Specific interventions examined included patient satisfaction, waiting times, length of stay, cost effectiveness and diagnostic interpretations.

Powers et al., (1984) conducted the first experimental field study of nurse practitioners with a small sample of 62 patients. Their study compared knowledge, satisfaction and compliance in emergency room patients based on whether they were cared for by nurse practitioners or physicians. Data were collected by structured interviews at two weeks and three months following the acute care episode. Overall they found there to be no significant difference between the two groups in regards to compliance scores or resolution of health problems. The study demonstrated the nurse practitioner patient group had greater comprehension of diagnostic recommendations and therapeutic applications. In regards to satisfaction, the nurse practitioner patients were more satisfied (77% vs 48%) compared with the physician group when it came to quality of care issues.

Cooper et al., (2002) studied a convenience sample of a patient cohort (n= 199) with minor injuries that were randomised to E-NP care or medical led care. Primary outcomes evaluated were patient satisfaction, clinical documentation, and unplanned follow up and missed injuries. Outcomes were measured over a period of two months using patient satisfaction scores, quality of clinical documentation using an audit tool and a one-month follow up survey. The study demonstrated high levels of patient satisfaction and clinical documentation quality with E-NP care when directly compared with medical led care.

Sakr et al., (1999) conducted an RCT that examined E-NP care compared with medical care with a large cohort of patients (n= 1453). The primary outcome measured was adequacy of care for patients with minor injuries who were managed by an E-NP or a junior doctor in the ED. History taking, examination of the patient, and interpretation of radiographs, treatment decision, advice and follow up were measured. Secondary outcomes measures were patient satisfaction, improvement and return to functional activities and unplanned representations. The authors concluded that E-NPs provided care for patients with minor injuries that was equal to or in some ways better than that provided by junior doctors. Nurse practitioners were reported to be better at recording medical histories and fewer patients had to seek unplanned follow up.

The local Australian study conducted by Chang et al., (1999) conducted an RCT exploring the local context of the quality of E-NP care (n=232). The pilot study used experienced emergency nurse clinicians working in a role considered to be that of a NP role for the study. The primary outcome measured was whether E-NPs could provide a level of care to patients with limb trauma and wound management in a rural ED. The study demonstrated no significant differences between E-NP and medical care in relation to patient's satisfaction and in all areas of patient care. Chang et al., (1999) also found that E-NPs followed the designated protocol for all of their patients and there were no significant differences in waiting times between the E-NP and medical care patients.

The major limitations in all of the three studies reviewed include the varied definitions used to describe the role of the E-NP. None of the studies provided a consistent operational definition for NPs and over the time period of these studies there was no legal protection of the NP title. Chang et al's (1999) study used emergency nurse clinicians working as advanced practice nurses. The lack of operational definition for advanced practice nursing and the international confusion related to this term prohibits comparisons with contemporary Australian NPs. In the UK, the title NP is not legally protected which lends itself to any nurse using the title with impunity. The variability of the clinical skills and theoretical knowledge of the nurses participating in the above studies is a significant limitation. In Australia, title protection for nurse practitioners has been legislated since 2000 and regulation was managed at state/territory level. With national health practitioner regulation in 2010, only nurses registered and endorsed by the Australian Health Practitioner Regulation Authority can practice as an NP (Nursing and Midwifery Board Australia, 2012).

These early E-NP studies also have limited application to the Australian contemporary health landscape. Originally E-NP service was introduced to address service gaps in primary healthcare. Currently, these roles have been incorporated into ED models of care due to a myriad of service issues such as overcrowding, increased demand and the challenges of meeting performance targets (National Health Performance Authority, 2013). Health services today are focusing on quality of patient care in the ED and the ability to deliver timely and efficient healthcare to all patents. The National Health Reform agenda has implemented the new National Access Target for Emergency Departments, known as the 'National Emergency Access Target' ('NEAT') in 2012. The NEAT is measured as the percentage of patients who leave the ED within 4 hours of their arrival. The time is measured from when the patient arrives at the ED to the time the patient has been admitted to a ward, transferred to another hospital, or goes home. The initial compliance target for 2012 was set at 72% with expectations of that figure gradually increasing to 90% by the year 2015 (Your Health, 2013). The recently implemented NEAT targets have forced health services to re-evaluate their delivery of care and evaluate their service models. Time-based performance targets such as wait times and length of stay (LOS) measures are utilized nationally to compare and benchmark health service efficiency.

There is a substantial gap in the research evaluating the effectiveness of E-NP service on outcomes, quality of patient care and service responsiveness within Australia and abroad. This paucity of research lends itself to the development of a robust strategy to review the literature and critically analyse the research to provide context for further studies. Hence for this project a SR was conducted to provide the latest scientific evidence on E-NP clinical and service effectiveness.

2.5 Publication 1 - Systematic review of the research literature

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The impact of nurse practitioner services on cost, quality of care, satisfaction and waiting times in the emergency department—A systematic review

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PROOF

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2.5.1 Introduction

A systematic review is considered a key element of evidence-based healthcare that informs a clearly formulated question (Collaboration, 2011). According to the hierarchy of evidence, a systematic review of RCTs is at the top tier of the pyramid proving the most valuable resource when exploring a question to be evaluated (Suny Downstate, 2013). This systematic review was therefore designed and conducted to critically appraise the quality of the existent literature surrounding E-NP service effectiveness based on the paucity of literature reviewed above. This review identified 14 relevant studies, appraised their quality and summarised the evidence by the use of an explicit methodology. The review findings provide up to date knowledge of best evidence surrounding E-NP service effectiveness and lays the foundation for research undertaken in this PhD.

The aim of this review was to establish the national and international evidence relating to the effectiveness of E-NP on service outcomes and quality of patient care. The manuscript was accepted for publication in July, 2014.

2.5.2. Contribution of authors

This manuscript presents the systematic review lead by myself under the supervision and guidance of my primary supervisor Professor G. Gardner. The author team was: N Jennings, S Clifford, A Fox and J O'Connell. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship that includes: substantial contribution to the conception of the review; the acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (Editors, 2014). I initiated the concept of undertaking a systematic review with a team of PhD students while participating in a postgraduate nursing forum at Queensland University of Technology, in February 2013. All members of the team were in varying stages of their candidacy and all exploring topics associated with health services

research and specifically nurse practitioners. I mentored the authorship team and lead the study design, search strategy, analysis and lengthy journal peer review process. I engaged all team members, (who resided in three different states of Australia), to produce a paper that has been peer reviewed and accepted by a journal ranked in the top 2 nursing journals (Reuters, 2014). I anticipate this initial collaboration of PhD students will continue to develop and produce highly regarded nurse practitioner research into the future.

2.5.3 Published manuscript

Title

The impact of nurse practitioner services on cost, quality of care, satisfaction and waiting times in the emergency department- a systematic review.

Abstract

Aims: To provide the best available evidence to determine the impact of nurse practitioner services on cost, quality of care, satisfaction and waiting times in the emergency department for adult patients.

Background: The delivery of quality care in the emergency department is emerging as one of the most important service indicators in health delivery. Increasing service pressures in the emergency department have resulted in the adoption of service innovation models: the most common and rapidly expanding of these is emergency nurse practitioner services. The rapid uptake of emergency nurse practitioner service in Australia has outpaced the capacity to evaluate this service model in terms of outcomes related to safety and quality of patient care. Previous research is now outdated and not commensurate with the changing domain of delivering emergency care with nurse practitioner services.

Data sources: A comprehensive search of four electronic databases from 2006-2013 was conducted to identify research evaluating nurse practitioner service impact in the emergency department. English language articles were sought using MEDLINE, CINAHL, Embase and Cochrane and included two previous systematic reviews completed five and seven years ago.

Review methods: A three step approach was used. Following a comprehensive search, two reviewers assessed all identified studies against the inclusion criteria. From the original 1013 studies, 14 papers were retained for critical appraisal on methodological quality by two independent reviewers and data were extracted using standardised tools.

Results: Narrative synthesis was conducted to summarise and report the findings as insufficient data was available for meta-analysis of results. This systematic review has shown that emergency nurse practitioner service has a positive impact on quality of care, patient satisfaction and waiting times. There was insufficient evidence to draw conclusions regarding outcomes of a cost benefit analysis.

Conclusion: Synthesis of the available research attempts to provide an evidence base for emergency nurse practitioner service to guide healthcare leaders, policy makers and clinicians in reform of emergency service provision. The findings suggest that further high quality research is required for comparative measures of clinical and service effectiveness of emergency nurse practitioner service. In the context of increased health service demand and the need to provide timely and effective care to patients, such measures will assist in evidence based health service planning.

Keywords: review, nurse practitioners, emergency service, quality of health care, patient satisfaction.

What is already known about the topic?

- There is limited evidence evaluating the effectiveness of the emergency nurse practitioner role in the current emergency department context.
- Previous reviews are now out-dated and it is essential for the evaluation of the evidence regarding emergency nurse practitioner service effectiveness and quality.
- The nurse practitioner role has evolved from a need to fill medical shortages, to an alternative model of care that can positively impact patient quality of care

What this paper adds?

- The delivery of quality of care in the emergency department is one of the most important service indicators to be measured in health services today.
- This review has shown that emergency nurse practitioner service has a positive impact on quality of care, patient satisfaction and waiting times. There is insufficient evidence to draw conclusions regarding outcomes of a cost benefit analysis.

Main text of manuscript

Introduction

Overcrowding, access block, the growing burden of chronic diseases in the community and reduced access to primary healthcare have all contributed to increased demand for emergency department services (Health Workforce Australia, 2012, Sprivulis et al., 2006, Lowthian et al., 2011). Increasing service pressures have resulted in the adoption of innovative service models; the most common and rapidly expanding of these is emergency nurse practitioner service. Evidence evaluating the effectiveness of the emergency nurse practitioner role has previously been found to be, ill-defined and the methodologically quality is considered to be fair to poor (Wilson et al., 2009). Clinical relevancy to the current emergency department context is essential for evaluation of emergency nurse practitioner service effectiveness and quality.

Background

Promoting the concept of healthcare reform and active consumer involvement, advanced nurse practice roles were developed to improve the quality of clinical care (Comiskey et al., 2014) . The nurse practitioner is one such role providing a service model that claims to offer flexibility and adaptation to the changing needs of the consumer population, but there are scant robust evaluations to date on the effectiveness of these roles. The nature of the nurse practitioner role involves a hybrid advanced nursing model of care which includes a combination of nursing care, diagnostic activities, intervention-based treatments and the use of medicines; some of these activities have traditionally been limited to the scope of medical practitioners (Gardner et al., 2010).

The nurse practitioner role was first established globally in the USA and Canada over 40 years ago, to augment a shortage of primary care physicians (Silver et al., 1967, Kleinpell and Goolsby, 2012) in under-serviced areas. As a result of lack of primary care access for patients, nurses expanded their scope of practice through education and credentialing to meet population needs (Ridgway, 2012). Nurse practitioners now work in a myriad of settings providing care across primary, secondary and tertiary contexts (American Association of Nurse Practitioners, 2011). As nurse practitioner services have developed, sub speciality areas such as emergency, cardiovascular, endocrinology and oncology have adopted the nurse practitioner role for the delivery of high quality patient care (American Academy of Nurse Practitioners, 2010). The nurse practitioner role in Australia was first developed in 1994 with a pilot project to address feasibility within the health context (Currie et al., 2007). Since this inception, there are now over 1000 endorsed nurse practitioners, protected by title legislation and working to generic competency standards that govern practice across a variety of clinical settings (Nursing and Midwifery Board Australia, 2014a).

Measuring the quality of patient care in the emergency department is emerging as one of the most important service indicators in Australian health services today. Emergency departments have seen more than 7% growth in patient presentations over the last 5 years and this has contributed

to an ever-growing burden on the delivery of quality patient care (Lowthian and Cameron, 2012). The capacity of emergency departments to deliver timely, high quality and consistent patient care is impacted by the increase in the number and complexity of presentations (Lowthian and Cameron, 2012). Emergency department overcrowding is seen as the greatest single impediment to safe and efficient emergency services in Australia and New Zealand (Cameron et al., 2009) significantly resulting in increasing waiting times, adverse events, mortality and hospital length of stay (Forero et al., 2010). National clinical indicators for emergency department service delivery are government mandated and designed to monitor, analyse and evaluate a health service's performance (Department of Health Victoria, 2012). There are defined clinical indicators compiled by the Australian Council of Healthcare Standards (ACHS) to provide clinical perspectives on trends in service and measures to improve quality and safety of patient care. Emergency department overcrowding has resulted in the clinical quality indicators of waiting times, length of stay, time to analgesia and mortality becoming adversely affected and impacting effectiveness of patient care (Lowthian and Cameron, 2012).

Major recommendation from the Australian Health Workforce Advisory Committee's evaluation of emergency department models of care (Australian Health Workforce Advisory Commitee, 2006) was the need to address service issues in the emergency department with innovative models and workforce reform. Implementation of emergency nurse practitioner service is part of a reformative model of health service that has the potential to directly impact service outcomes and quality of patient care (Wilson et al., 2008).

The rapid uptake of emergency nurse practitioners internationally has outpaced the capacity to evaluate this service model in terms of outcomes related to safety and quality of patient care. For example, the emergency nurse practitioner model is the fastest growing nurse practitioner model in Australia, with a 61% increase over a three years period (Middleton et al., 2011). With increasing patient demands for service, and health care reform high on the government agenda, the provision of quality care and health service performance needs to be addressed.

There is a significant gap in the international research evaluating the effectiveness of emergency nurse practitioner services on waiting times, cost, quality of care and patient satisfaction. Carter and Chochinov (2007) and Wilson, Zwart, Everett and Kernick (2009) synthesised the evidence in the form of two systematic reviews exploring clinical effectiveness of nurse practitioners in the emergency department setting. Wilson et al.'s (2009) meta-analysis of pooled data from 55 studies, showed no significant differences in the clinical effectiveness of nurse practitioners to mainstream management of minor injuries. Carter and Chochinov's (2007) narrative synthesis of available evidence suggested that nurse practitioners services can reduce waiting times for the emergency department, lead to high patient satisfaction and provide a quality of care equal to that of a mid-grade resident medical officer. When comparing the cost of emergency nurse practitioner services with resident physicians it was determined that nurse practitioner services were more expensive. The results confirmed earlier findings from the US and UK studies where the role has been established for several decades (Sakr et al., 1999, Cooper et al., 2002, Barr et al., 2000, Mabrook and Dale, 1998, Asubonteng et al., 1995, Byrne et al., 2000). With the increasing uptake of emergency nurse practitioner service internationally since the previous reviews, coupled with imperatives for emergency department service improvement, it is timely to re-examine the evolving evidence on clinical and service effectiveness of emergency nurse practitioner services for today.

The review

Aim

Systematic reviews provide a rapid overview of the significance of the research topic and an evaluation of the quality of the individual studies included in the review (Ressing et al., 2009). This systematic review was conducted to determine the best available evidence related to the impact of emergency nurse practitioner services on cost, quality of care, satisfaction and waiting times in emergency departments. This review will consolidate the evidence presented previously by Carter and Chochinov (2007) and Wilson et al. (2009) and review the new literature from 2006 to 2013.

Design

A systematic review with a narrative analysis (Ressing et al., 2009), was conducted to locate, retrieve and evaluate the international evidence on effectiveness of emergency nurse practitioner service A detailed study protocol, analysis plan and a prospectively defined inclusion and exclusion criteria was developed by the review team. Due to the heterogeneity of the available research and lack of complete and comparable statistical data, a narrative synthesis of study findings was conducted with a quantitative summary of the results included. Critical appraisal tools, the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI), were used.

Search Strategy

The systematic reviews published in 2007 and 2009 were considered to be comprehensive and hence the new search strategy for this review was mandated from the 2007 paper methodology to include all articles and all new evidence that would not have been reflected upon in the original two reviews. It was also considered that the healthcare context and evolving role of emergency nurse practitioner services had also moved forward from this previous era and would no longer be considered valid for this review. A comprehensive search strategy was undertaken in May 2012 and again in March 2013 to locate both published and non-published studies from 2006 to 2014. A search of the literature was undertaken by developing a concept map to recognise all the key subject words and concepts. The corresponding author of the previous systematic review published in 2007 (Carter et al., 2007) was contacted to share search strategy techniques from the initial review. A three-step search strategy was formulated to identify the literature gained through the strategy that included keyword, subject and grey literature searching. Initial keyword terms used were combined to yield our search results. The key search terms are shown in Table 1. MeSH terminology and keywords were adapted to suit the needs of each database searched.

An initial search included identifying synonyms of the keyword terms utilising each databases' thesaurus options to ensure all terms were broad enough to capture the research pertaining to the

field of emergency nurse practitioner service outcomes. The databases searched were MEDLINE, CINAHL, Embase and Cochrane.

Table 1. Summary of the themes and key words employed in the literature review

Key themes	*Role title*	*Setting*	*Effectiveness*
	nurse practitioner* Advanced practice nurs* nurse clinician nurse consultant	Emergency department accident and emergency emergency medical service* emergency casualty emergency room minor injury clinic	outcome and processes results benefits deliverables quality of health care evaluation impact* efficien* follow up studies quality assurance treatment outcomes nurs* outcomes cost satisfaction wait time* pain analgesia

A second extensive search using all identified keywords and subject terms were then undertaken using all of the databases. A further electronic search of Google, Google scholar and health department websites internationally for nurse practitioner published works, reports or additional research was also conducted.

Inclusion Criteria

Published and unpublished English language studies which met the following criteria, were eligible for inclusion in the review

Table 2 Inclusion Criteria using PICO format

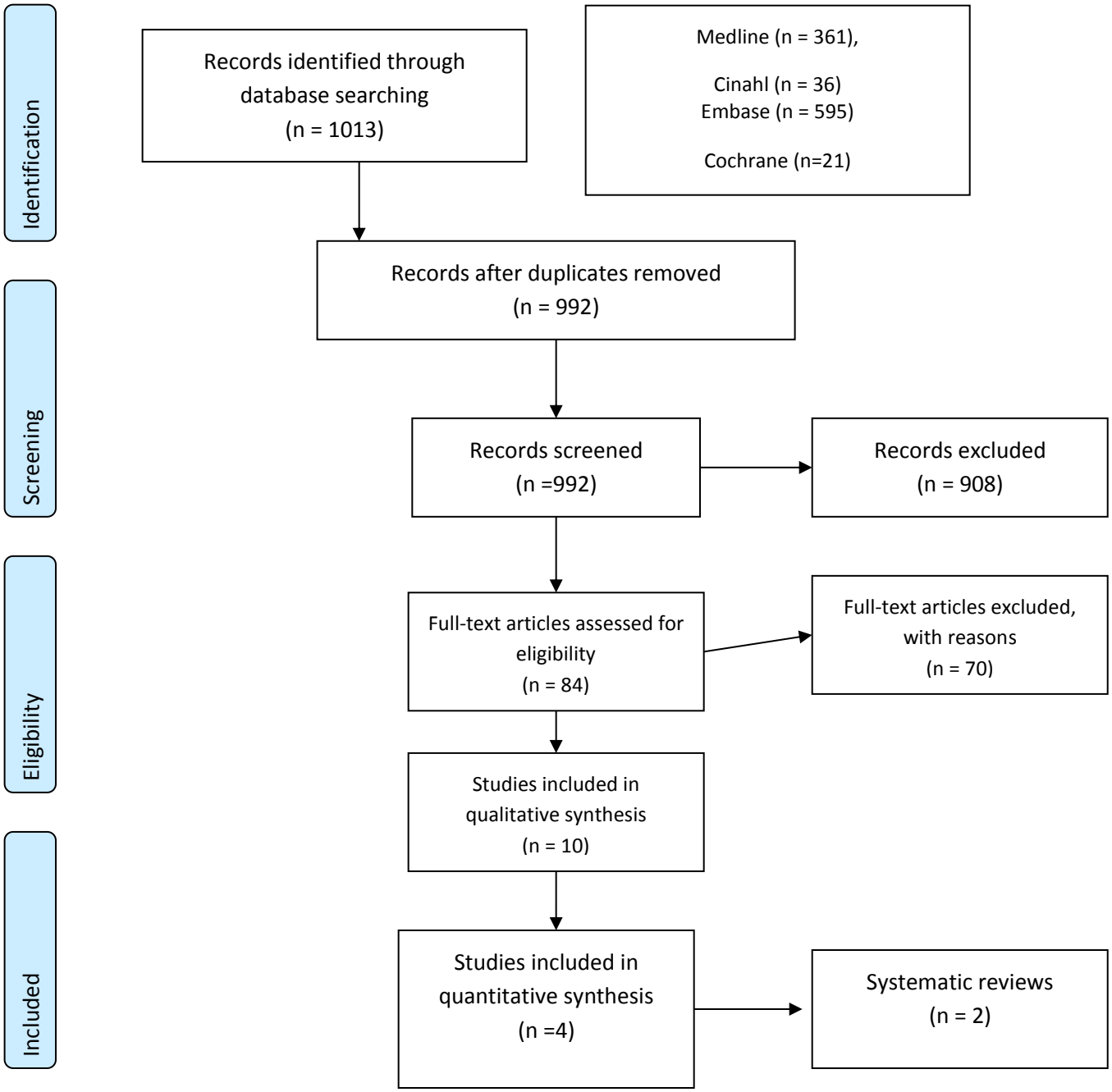
P (population)	All facilities with defined emergency services, i.e. Minor injuries clinic, walk in centers, emergency departments, accident and emergency, casualty, primary care clinics. Adult male and female patients and ethnicity.
I (intervention)	Nurse practitioner services conducted on site.
C (comparisons)	Traditional emergency department clinical services that do not include nurse led care, only medical lead services (comparator).
O (outcomes)	The primary outcomes are impact of nurse practitioner services (intervention) on o cost o waiting times o patient satisfaction o quality of care

There are many definitions of the nurse practitioner role internationally. Hence the term nurse practitioner is often used interchangeably with advanced practice nurse, registered nurse, acute care nurse practitioner, family nurse practitioner, nurse registrar, nurse consultant and nurse practitioner candidate. In Australia the term nurse practitioner is title protected by national legislation and less ambiguity exists in local literature regarding its definitions (Nursing and Midwifery Board Australia, 2010). All definitions were considered during the search strategy and then hand reviewed for identification of the appropriate use of the term nurse practitioner.

Search outcome

The reference lists of all identified abstracts were also searched for additional material not already located. The initial search of the above strategy yielded 1013 articles. These articles were then hand reviewed by the primary author for relevance to the aims of the review. Retained articles were then assessed for relevance to the review based on the title and the abstract using the inclusion criteria. Articles identified as potential for inclusion were then retrieved yielding a total of 84 articles. A two-person review process was then undertaken to identify the final articles for review. Based on the assessment of the full text, those studies of poor methodological quality, and those that did not meet the inclusion criteria were excluded from the review. Fourteen studies were included in the review examining nurse practitioner service impact on cost, quality of care, satisfaction and waiting times. Two articles were disputed in the two-person review process and sent to a third reviewer for analysis (Figure 1). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram has been utilised to demonstrate the flow of information through the different phases of the review (Moher et al., 2009).

Figure 1. Systematic review search flow diagram



There was consensus in the review team that 14 papers met the inclusion criteria (Table 2). Two of the 14 papers were considered to be of the highest level of evidence, as they were systematic reviews (National Health and Medical Research Council, 2000). There were two quasi-randomised controlled trials and the remaining 10 studies were observational descriptive designs that included retrospective audit, case control and case series.

Quality appraisal

Two independent reviewers using standardised data extraction tools adapted from the Johanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) assessed the quality of the included studies. Any disagreement was resolved by discussion between the two reviewers and sent to a third reviewer for mediation if required. The quasi-randomised trials were evaluated to determine assignment of randomisation, blinding, allocation concealment, validation of study tools, intention to treat principles and study limitations. The remaining descriptive studies were appraised using the same approach to quality and to determine differences between populations, comparators to the intervention and resultant outcomes. All data extracted included specific details about the interventions, populations, study methods and outcomes of significance in relation to the impact of emergency nurse practitioner services on cost, quality of care, satisfaction and waiting times in emergency departments. The findings from the studies were then summarised by two reviewers and then combined to form the narrative review.

Data abstraction

Data was extracted from each of the 14 included studies and presented in Table 3. Summary of the aims and methodology, participants, outcomes and results for each study was tabled. Data was extracted by one reviewer and checked by a second reviewer for accuracy. Table 4 is a synthesis of the results of the included studies.

Table 3. Included studies objectives and measurements.

Study	*Aims*	*Data collection Methods*	*Participants*	*Outcomes*
McClellan et al (2012)	To investigate the clinical effectiveness of extended scope physiotherapists, emergency nurse practitioners and doctors, who independently manage minor injuries in a United Kingdom Emergency Department.	Randomised pragmatic trial of equivalence using a questionnaire attached to patients notes completed by treating practitioners, outlining treatment and process measures and follow up. Follow up was assessed by telephone interviews at 2 and 8 weeks post discharge.	All adults >16 years presenting with a peripheral soft tissue injury eligible for management by any of the three groups. 372 patients provided consent and were randomised, 126 to extended scope physiotherapists group, 123 to emergency nurse practitioner group and 123 to doctor group.	The primary outcome measure was functional recovery. Primary outcomes were assessed using a Disability of the Arm, Shoulder and Hand (DASH) scoring tool and a Lower Extremity Functional Score scoring tools. Secondary outcomes measured were quality of life, health utility score and number of days unable to work. Additional outcomes reported include time spent with each practitioner, the frequency with which various treatments and drugs were used and subsequent contact with other healthcare providers.
McClellan et al (2013)	To investigate the cost effectiveness of emergency nurse practitioners and extended scope physiotherapists with	Randomised pragmatic trial of equivalence using a questionnaire attached to the patients notes completed by treating practitioners, outlining	All adults >16 years presenting with a peripheral soft tissue injury eligible for management by any of the three groups. 372 patients provided consent and were	Main outcome measures were economic cost evaluation from a funder perspective capturing the direct, indirect and intangible costs in primary and secondary care associated with patient care episodes.

	routine care by doctors when treating soft tissue injuries in a single United Kingdom emergency department.	treatment and process measures. Plus follow up telephone interviews using a questionnaire. Full methodology was not outlined in this paper but in the companion paper listed above.	randomised, 126 to extended scope physiotherapists group, 123 to emergency nurse practitioner group and 123 to doctor group.	Primary outcome were cost per hour of patient contact and cost per patient per hour. This was calculated by dividing the salary cost of the different professional groups by their productivity i.e. numbers of patients treated per hour. Secondary outcomes were the indirect cost per hour of patient contact and the indirect costs of care per hour of patient contact.
Dinh et al (2012	Primarily a study of the overall quality of care delivered by a fast track unit and secondly to compare quality of care provided by a dedicated	Observational study using a convenience sample. Patients enrolled in the study completed a patient satisfaction survey immediately post	Patients aged between 16 and 70 years presenting to fast track when the nurse practitioner was working. 320 patients enrolled, 155 seen by doctors and 165	Patient randomised by triage nurse into two groups- ENP and DR group. Quality of care was measured using 1. Patient satisfaction scores 2. Overall care rating at the point of discharge 3. Health status at two week follow up

	emergency department nurse practitioner and emergency doctors.	treatment, follow up surveys were completed two weeks following discharge from the hospital.	seen by the nurse practitioner.	4. Adverse events. Primary outcome was quality of care using patient satisfaction scoring, patient satisfaction scoring adjusted for time waiting, patient health status perception two weeks post discharge and unplanned representations and missed fractures.
Colligan et al (2011)	To determine if nurse practitioners are as effective as Emergency Medicine Registrars in managing minor injuries in a New Zealand setting.	Prospective observational chart audit of non-consecutive patients with minor trauma. Chart review and data entry attended by an emergency nurse practitioner and emergency registrar.	All adult >15 years patients seen during nurse practitioner working hours (0900-1930 7 days a week) Nurse practitioner group n=305 and doctor group n= 115. Median age nurse practitioner group 30 and doctor group 41.	Primary outcome measure was LOS. Secondary outcomes were time to be seen, number of unexpected returns, missed injury rate and numbers of patients who left without being seen
Fry et al (2011)	To describe patient demographics and conditions managed within a transitional emergency nurse practitioner model, evaluate the impact of the transitional emergency	A single institution prospective observational study over 12 months. Data on patient demographics, triage categories and conditions managed by Transitional Emergency Nurse	3827 patients managed by transitional emergency nurse practitioner model = 10% of emergency department presentations. All data was collected from electronic emergency management program	Patient demographics and conditions managed within the transitional emergency nurse practitioner model were analysed using descriptive statistics. The efficiency and safety of transitional emergency nurse practitioner model management was analysed by comparing wait times and length of stay for a random selection of diagnostic patient groups and then compared with those seen by

	nurse practitioner model role on the delivery of emergency services and to examine the efficiency and safety of transitional emergency nurse practitioner model management.	Practitioners was collected from the emergency department information system and compared with patient flow through the department for the 12 months prior to the transitional emergency nurse practitioner model implementation.	reports.	doctors in the time leading up to implementation of the transitional emergency nurse practitioner model. Safety was evaluated by examination complaints and incidents pertaining to transitional emergency nurse practitioner model performance, auditing representations and checking of all transitional emergency nurse practitioner model radiological investigations by emergency physicians.
Van Der Linden et al (2010)	To compare care provided by nurse practitioners and junior doctors/senior house officers to patients with minor injuries and illnesses.	Descriptive retrospective cohort study. All data was collected from hospitals electronic patient database. Comparison of missed injuries, inappropriate management, waiting times and length of stay.	Sample of 741 patients managed by nurse practitioners and 741 patients managed by junior and senior doctors. All patients deemed low care	Groups compared regarding incidence and severity of missed injures and inappropriately managed cases, waiting time and length of stay.
Jennings et al (2009)	To explore patients' satisfaction with care provided by emergency nurse practitioners and emergency department	A self-administered 16 question survey about the patient emergency department experience including timing,	All patients presenting to fast track area of emergency department during a 4 month period. 202 patients completed the survey, 103	Patient satisfaction Questionnaire responses indicated practitioner interest and understanding, patient confidence and reassurance from consultation, discussion thoroughness, and management, planning and family inclusion.

	doctors.	education, follow-up, instruction.	seen by emergency nurse practitioners and 99 seen by emergency doctors.	Responses on a Likert scale were compared.
Steiner et al (2009)	To determine if a broad scope nurse practitioner in an emergency department would improve wait times, length of stay and left-without-treatment rates	Prospective observational study Data collected from the emergency department information system database was analysed using descriptive statistics.	Intervention shifts were those when a nurse practitioner was rostered in the emergency department, control shifts were those when only emergency physician was working. All patients registered in the ED during control and intervention shifts were eligible for analysis. 1325 patients seen by doctors and 379 autonomously by nurse practitioners and 220 and in	Primary outcomes of patient wait times, length of stay and patients whom left-without-treatment were compared between nurse practitioner and doctor shifts.

			collaboration.	
Considine et al (2010)	To evaluate the effect of clinician designation on emergency department fast track performance	A retrospective audit of patients managed through an emergency department fast track unit.	All patients seen in Emergency Department Fast Track during a 12 month period. (n=8714).	Waiting times, in relation to recommendations in the Australian Triage Scale. Length of stay, for non-admitted patients.
Jennings et al (2008)	To assess the impact of the implementation of the emergency nurse practitioner candidate on waiting times and length of stay for patients presenting to the emergency department compared with the traditional model of care	Retrospective case series study of emergency department patients in common diagnostic subgroups. Data collected from emergency department patient information system and descriptive statistics were used to analyse the results.	Patients with Australasian Triage Scale 3-5 categories presenting to the emergency department between 0700-2330 all days except Tuesdays. (n=3156) 572 in the nurse practitioner candidate managed group and 2584 in the doctor managed group.	Primary outcome were; time waiting to be seen by a nurse practitioner candidate or a doctor and length of stay, and Disposition comparisons.
Considine et al (2006)	To compare emergency department waiting times, treatment times and length of stay for patients managed by an emergency nurse practitioner candidate	Case control study	Patients were selected from the 3 most common emergency department discharge diagnoses for emergency nurse practitioner candidate managed patients.	Primary outcomes measured fell under the heading of patient flow. This was achieved though the comparison of waiting times, treatment times and length of stay between emergency nurse practitioner and doctor (traditionally) managed patients.

	with patients managed by the traditional emergency department model of care.		Hand/wrist wounds, hand/wrist fractures and removal of POPs. Emergency nurse practitioner group n=102. Control or traditional emergency management group n = 623.	
Nash et al (2006)	To evaluate the efficacy of a newly developed fast track unit staffed by nurse practitioners.	An explorative descriptive design utilizing retrospective electronic chart review and prospective patient satisfaction surveys and comparing the new fast track unit with the replaced minor care treatment area.	All patients attending the fast track unit between March and August 2003, n= 5995 comparison with the minor care treatment area patient presentations for the same period in the prior year, n=9130.	Primary outcomes were the measures of unscheduled returns, left without being seen, patient satisfaction, time in the emergency department and time in the treatment area.
Wilson et al (2009)	Systematic review		The best available evidence to determine the clinical effectiveness of emergency nurse practitioners in treating minor injuries. 9	Primary outcomes compared the clinical effectives of nurse practitioners to junior emergency doctor or mainstream management of minor injuries was determined with fair to poor methodological quality.

			studies including 2 randomised control trials from 55 papers in the literature search met the inclusion criteria.	
Carter and Chochinov (2007)	Systematic review		Articles that discussed nurse practitioners in the emergency department settings that addressed 1 or more of 4 outcomes: cost, quality, wait times and patient satisfaction. 36 papers were included	4 key outcome measures: wait times, patient satisfaction, quality of care and cost effectiveness. Determined inclusion and allowed for comparison

Results

Cost

From the 14 papers included in the review, only one directly examined cost of delivery of emergency nurse practitioner services and their comparison to the same / similar service provision by medical and extended scope physiotherapist personnel. McClellan et al. (2013), in their randomised pragmatic trial of equivalence, measured costs in management of the soft tissue injury patient cohort. The authors acknowledge the significant limitations of the study being limited to one site with small nurse practitioner numbers and question the extent to which findings could be generalised. The overall outcome was that cost of soft tissue injury management was equal between medical, nurse practitioner and extended scope physiotherapist services.

Quality of care

The effectiveness of emergency nurse practitioner services on quality of care was poorly defined in the review with only one study using the term as an outcome measure (Dinh et al., 2012). A convenience sample of patients was randomised to either medical or the emergency nurse practitioner care in the fast track unit of the participating emergency department. Quality of care was measured in this study as a combined score from patient satisfaction; follow up health status and adverse event rates. This was a well-designed study that demonstrated overall quality of care rating of emergency nurse practitioner care at 68% compared with 50% for the medical care group ($p<0.020$). In particular there was some evidence to suggest the overall care rating categorised were significantly different between the emergency nurse practitioner service group and medical officer service group of patients. The emergency nurse practitioner patient group rated their care as excellent compared with the medical care patient group (68% vs. 50%, fisher's exact $p< 0.02$).

Measures utilised throughout the other studies that were often used interchangeably with quality of care definitions, included accuracy of X-ray interpretation, unexpected patient returns, missed injuries rates, inappropriate management of patients, unscheduled returns to emergency department and percentage of patients whom do not wait for treatment (Nash et al., 2006, Colligan et al., 2011, Dinh et al., 2012). Fry et al.'s (2011) study demonstrated a reduction the number of patients' whom did not wait for treatment during service delivered by the nurse practitioner service. Nash et al.'s (2006) study showed a rate of unscheduled returns for emergency nurse practitioner patients of 2.3% compared with 4.2% for the medical patients. Colligan et al. (2010) demonstrated similar figures of 2% for the emergency nurse practitioner patient group and 1% for the medical registrar patient group. Missed injuries and inappropriate management were also examined in Colligan et al.'s (2010) study. No significant difference was found between the emergency nurse practitioner service and physician service groups.

Satisfaction

Patient satisfaction for care delivered by emergency nurse practitioner services was explored in Dinh et al.'s (2012) observational study. The study used a convenience sample of emergency patients randomised to assessment and treatment by an emergency nurse practitioner or an emergency medical officer. Satisfaction surveys were completed by 236 patients presenting to the emergency department and comparisons made between randomised treatment groups of either an emergency nurse practitioner (n=133) or the next available emergency medical officer (n=103). Findings showed that improved quality of care, reduced waiting times and consequently higher patient satisfaction levels were all apparent in the emergency nurse practitioner service group. When satisfaction scores were adjusted for waiting time the emergency nurse practitioner service still maintained a 1.5 x higher mean total satisfaction score (beta coefficient = 1.5, p = 0.004, 95% CI, 0.48-2.5).

These results are supported by the study conducted by Jennings et al. (2009) utilising a similar sample size. Jennings et al.'s (2009) observational survey of 202 emergency department patients reported significant differences in levels of satisfaction between patients assigned to emergency

nurse practitioner care and emergency department physician care. Out of the 16 questions, responses to 12 demonstrated a significant between the two groups in favour of the emergency nurse practitioner services ($p<0.005$). The survey questions related to the health professional being interested in the person, being thorough, the patient being less worried about their health after seeing the health professional and having enough time to discuss concerns in detail.

Nash et al.'s (2006) report on patient satisfaction with care management in a new fast-track unit staffed only by emergency nurse practitioners, surveying 90 emergency department patents. Patients were asked six questions as part of a patient satisfaction questionnaire and the results aligned with demographic data collected from historical records. The research reports that 100% of patients seen by emergency nurse practitioner services in the fast-track area scored their care as good or excellent.

Waiting times

Waiting time analysis was well reported and homogenous amongst the included papers. Of the 14 papers, nine explored emergency nurse practitioner services' impact on waiting times. In the most recent study by McClellan et al. (2012) , a randomised pragmatic trial of equivalence, showed a similar wait time profile for patients managed by the emergency nurse practitioners in comparison to medical officers and extended scope physiotherapists. In contrast, Dinh et al. (2012) reported that patients managed by emergency nurse practitioners trended to shorter waiting times when compared with medical officers, with a difference of seven minutes ($p=0.06$). Colligan et al.'s (2011) prospective observational audit demonstrated a significant reduction in waiting time for patients managed by the emergency nurse practitioners in comparison to the emergency department medical registrars; emergency nurse practitioners 14 minutes (range 5-27) vs. emergency department medical registrars 50 minutes (range 21-78) ($p<0.0001$). This is also supported by Jennings et al.'s (2008) large case series which clearly showed a significant reduction in waiting times for patients managed by the emergency nurse practitioners service, 12 minutes (range 5.5 – 28 minutes), in comparison with traditional medical service, 31 minutes (range 11.5 – 76 minutes), ($p<0.001$). Waiting times reduction was also reported by Fry et al

(2011), Van Der Linden et al (2010) and Considine et al (2010). These results are consistent with the evidence presented in the preceding systematic reviews (Carter and Chochinov, 2007 and Wilson et al, 2009).

Some of the study settings were collaborative models of care that encompassed both emergency physicians and emergency nurse practitioner care and hence their outcomes of waiting times are difficult to interpret. Steiner et al.'s (2009) study used a collaborative model that demonstrated no significant differences in overall median waiting times, but also showed increased patient throughput with larger numbers of patient presentations being seen when the emergency nurse practitioner service was available. Considine et al.'s (Considine et al., 2006) case control study results are also difficult to synthesise. This study included only one emergency nurse practitioner candidate (a candidate has not yet completed the requirements to be endorsed as a nurse practitioner) and formed part of the evaluation of the implementation of the new service in this setting.

Table 4: Results and interpretations of included studies impact of nurse practitioner services on cost, quality of care, satisfaction and wait times.

Outcome measured	*Results*	*Interpretations*
<u>*COST*</u> *McClellan et al (2013)*	Principal findings determined that the average cost per hour of patient contact was £80.91 for doctors, £89.71 for extended scope physiotherapists and £109.81 for emergency nurse practitioners. The direct costs per hour of patient contact was £60.96 for doctors, £52.48 for extended scope physiotherapists and £55.21 for emergency nurse practitioners it is the indirect costs that extended the average cost in each group, namely planned follow up, travel costs, additional items such as pain relief and bandages. The results demonstrated that both the extended scope physiotherapists and emergency nurse practitioner groups could not be cheaper than routine care provided by doctors: they are at best equivalent and possible more expensive.	The findings are unlikely to represent all the United Kingdom emergency departments and encourage a multicentre replication. Study site was a single emergency department with relatively small numbers of practitioners involved in the research. Indirect costs were only captured to eight weeks post injury; the true costs may extend far beyond this in some of the sample.
<u>QUALITY OF CARE</u> *Directly measured by Dinh et (2012)*	Quality of care was measured using a combination of Patient satisfaction scores, Overall care rating at the point of discharge, Health status at two week follow up and Adverse events. Overall care rating emergency nurse practitioner 68% vs. 50% doctor (p=0.02).	Australian study. High quality care delivered by (only 1 emergency nurse practitioner at site), and quality of care was defined through a combination of separate outcomes and then combined to form 'quality of care' rating
Indirectly measured Colligan et al (2010)	Missed fracture rate was equivalent 1%. Unexpected return rate was 2% in the nurse practitioner group and 1% in the doctor group. Left without being seen rate was 5% during the study time frame, and	New Zealand study at one site. Potential for selection bias of patients into each group. Significant difference in sample sizes per groups.

	overall distribution of left without being seen rate was 30% during nurse practitioner in the department time and 70% when no nurse practitioner was in the department.	Use of electronically recorded times may not reflect true flow through the emergency department.
Nash et al (2006)	Unscheduled returns to the emergency department when first seen in the emergency nurse practitioner managed fast track unit was 2.3% compared to the overall emergency department return rate of 4.2% for the same period. Left without being seen rates were reported in the minor care treatment area at a rate of 6.7 % compared to the emergency nurse practitioner managed fast track unit at 3.9% ($p<0.001$).	USA Study. Mixed comparisons between two treatment areas and overall emergency department statistics.
Fry et al (2011)	Did not wait when the transitional nurse practitioner model operational 4.5% vs. 8.1% in previous year. Representing transitional emergency nurse practitioner model rate was 3.3%.	Australian study conducted at a single site. Data was dependant on correct data entry by staff. Possible selection bias.
<u>WAITING TIME</u>		
Dinh et al (2012)	Significant difference between study groups in the overall care rating 68% for nurse practitioners vs. 50% for doctors ($p=0.02$) and simile total satisfaction and total satisfaction adjusted for wait times remained statistically significant in favour of the nurse practitioner group, median score 23 in total satisfaction, compared with doctor group median score 21 in total satisfaction ($p=0.002$). Telephone responses to the general health component reported excellent health in the nurse practitioner group 31% vs. 13% in the doctor group ($p=0.015$). Physical component summary (PCS) and mental component summary (MCS) showed no significant difference between nurse practitioner	Australian study. High quality care delivered by (only 1 emergency nurse practitioner at site), patient satisfaction higher but overall health outcomes and adverse events rates were similar at two weeks follow up. Strongly supports an emergency department fast track unit structure.

	and doctor groups. (PCS 48 vs 47.6 p=0.78) (MCS 51.2 vs 51.7 p=0.58). Unplanned representations and missed fractures emergency nurse practitioner 9% group vs. 6% doctor group (p=0.22). Each group missed 1 fracture.	Single study site with low practitioner numbers.
Colligan et al (2011)	Time to be seen (median) nurse practitioner group14 minutes vs. 50 minutes in doctor group (p= <0.0001). Length of stay (median) 99 minutes nurse practitioner group vs. 139 minutes doctor group=<0.0001). Treatment times were equivalent. Missed fracture rate was equivalent 1%. Unexpected return rate was 2% in the nurse practitioner group and 1% in the doctor group. Left without being seen rate (LWOS) was 5% during the study time frame overall distribution of LWOS was 30% during nurse practitioner in the department time and 70% when no nurse practitioner was in the department.	New Zealand study. Potential for selection bias of patients into each group. Significant difference in sample sizes per groups. Use of electronically recorded times may not reflect true flow through the emergency department.
Nash et al (2006)	Unscheduled returns to the emergency department when first seen in the emergency nurse practitioner managed fast track unit was 2.3% compared to the overall emergency department return rate of 4.2% for the same period. Left without being seen rates were reported in the minor care treatment area at a rate of 6.7 % compared to the emergency nurse practitioner managed fast track unit at 3.9% (p<0.001). No significant difference between the emergency nurse practitioner managed fast track unit, 4.36hrs, and the minor care treatment area, 4.68hrs, for length of stay was determined. Statistical difference in treatment time of 1.97 hours for the emergency nurse practitioner managed fast track unit compared with 2.64 hours was minor care treatment area was shown.	USA Study. Mixed comparisons between two treatment areas and overall emergency department statistics. Dependant on data entered by clinicians at time of treatment.

McClellan et al (2012)	Primary outcomes Functional recovery- emergency nurse practitioners and extended scope physiotherapists had equivalent outcomes to routine care provide by doctors 8 weeks post injury. Secondary outcomes Nurse practitioners and extended scope physiotherapists were equivalent to routine care provided by doctors in all measures. Patients seen by emergency nurse practitioners had similar time profiles to doctors with extended scope physiotherapists having longer consultation times.	The study was limited to one United Kingdom emergency department, with relatively small numbers of practitioners, making generalisation of findings difficult. The follow up period was concluded at 8weeks post injury and important long-term issues may be being overlooked in the findings. Further multicentre studies will increase the validity of their findings.
Jennings (2008)	Significant reduction in waiting times and length of stay for nurse practitioner managed patients. Waiting times nurse practitioner was 12 minutes vs. 31 minutes ($p<0.001$) for doctor group, Length of stay for nurse practitioner group 94 minutes vs. Doctor group 170 minutes ($p<0.001$).	Limited to one Australian emergency department. Retrospective case series. Doctor group not located just in Fast track unit so may have had competing interests with other more complex patients adding to delays in waiting time and length of stay during the study period. Possible data collection inaccuracies. No consideration for other influences on data collected e.g. Access block.
Fry et al (2011)	Median transitional emergency nurse practitioner waiting time38 min compared with 59.7 min previous year. Length of stay was 207min vs. 213min. ($p=<0.0001$). Random comparison of length of stay between nurse practitioner patients and Doctor patients for musculoskeletal diagnosis. Nurse practitioner median length of stay 33min vs. 53min ($P=<0.0001$). Did not wait 4.5% vs. 8.1% in previous year. Representing nurse practitioner rate was 3.3%	Australian study conducted at a single site. Data was dependant on correct data entry by staff. Possible selection bias.

Van Der Linden et al (2010)	No statistical difference was found between the nurse practitioner or doctor group in terms of missed injuries or inappropriate management, 2.7% nurse practitioner vs. 1.2% doctors. No significant difference in waiting time 19mins nurse practitioners vs. 20mins doctors. Length of stay was longer for doctor 85min vs. 65mins for nurse practitioners (p=<0.001).	Netherlands study conducted at a single site. Nurse practitioners restrained in types of patients able to treat, no ambulance or GP referrals, greater percentage of patients less than 5yrs.
Considine et al (2010)	Patients managed by nurse practitioners and emergency physicians had significant shorter emergency department length of stay than those managed by junior doctors Nurse practitioners met NEAT 95.9% vs Interns 78.9%	Australian Study. Many variable results open to interpretation.
Steiner et al (2009)	No significant differences in overall median waiting times or length of stay. Did not wait rate 11.9% vs. 13.7% (Intervention/Control).	Canadian study. Many compounding factors that may have swayed recorded data e.g. Bed block.
Considine et al (2006)	No significant differences in median waiting time, Length of stay between nurse practitioner candidate and doctor managed patients. There was some variability between diagnostic subgroups in relation to waiting times and length of stay.	Australian study limited to a single site. Acknowledges that patient flow outcomes do not independently or accurately reflect the effectiveness of an emergency nurse practitioner candidate program.

SATISFACTION *Dinh et al (2012)*	Significant difference between study groups in the overall care rating 68% for nurse practitioners vs. 50% for doctors (p=0.02) and slimily total satisfaction and total satisfaction adjusted for wait times remained statistically significant in favour of the nurse practitioner group, median score 23 in total satisfaction, compared with doctor group median score 21 in total satisfaction (p=0.002).	High quality care delivered by (only 1 emergency nurse practitioner at site), patient satisfaction higher but overall health outcomes and adverse events rates were similar at two week follow up. Single site low practitioner numbers.
Jennings et al (2009)	Significant differences were reported in 12 of the 16 questions ($p<0.05$) in favour of the emergency nurse practitioner care provided. These 12 answers related to the doctor or nurse practitioner being interested in the person, being thorough, the patient being less worried about their health after seeing the doctor or nurse practitioner and having enough time to discuss concerns in details. The remaining answers favoured towards the nurse practitioner model without statistical significance, these responses related to management and planning.	Australian study Single site, greater validity in the findings might be obtained by combined multicentre study results.
Nash et al (2006)	Patient satisfaction 100% for quality for care given by emergency nurse practitioner managed fast track unit as good or excellent.	Compared the patient flow and satisfactions between an old well-established unit and the first 3 months of operation of the new emergency nurse practitioner managed fast track unit. Dependant on data entered by clinicians at time of treatment.
PREVIOUS REVIEWS *Wilson et al (2009)*	No statistically significant differences ($p<0.05$). When comparable data was pooled, there were no significant differences ($p<0.05$) between effectiveness of care of adults by emergency nurse practitioners and junior doctors.	The authors acknowledge that findings were limited to the limited number of poor quality studies and recommend conclusions be viewed with caution. Further research is encouraged.

Carter and Chochinov (2007)	Many findings leading to the conclusions that emergency department nurse practitioners are more expensive than residents however total costing is difficult as most nurse practitioners carry out the nurse treatment that residents do not. Quality of care was found to be equal if not better in certain work requirements. Improved communication with patients, shorter waiting periods and length of stay were seen to contribute to overall higher patient satisfaction levels with nurse practitioner treatment.	Further higher quality research is required to confirm and update findings.

Discussion

There is a paucity of evidence exploring the impact of emergency nurse practitioner services on cost, quality of care, satisfaction and waiting times in the emergency department. The lack of well-controlled studies evaluating these outcomes resulted in the inclusion of study designs other than randomised control trials necessitating narrative reporting of findings. The overall quality of the included studies was also difficult to compare due to the varying operational definitions in role titles, scope of practice and levels of interventions. Additional difficulties were found with the inherent small sample of emergency nurse practitioners in the often-single site observational designs.

Reliable evidence on the outcome measure of cost effectiveness is considered a major influence on service planning for expansion of emergency nurse practitioner services (Hollinghurst et al., 2006, McClellan et al., 2013). Results from the one study in this review that directly examined the cost of delivering emergency nurse practitioner service compared with medical and extended scope physiotherapist services (McClellan et al., 2012), require careful consideration. Interpreting equivalence of cost between these three different service providers requires a greater analysis regarding the type of funding model, role descriptions and a cost benefit analysis. Varying economic models fund emergency department budgets and hence direct comparisons to the UK, USA and Australian settings is problematic.

Emergency nurse practitioner services have shown to improve the performance indicators that directly impact patient quality of care (Wilson et al., 2009; O'Connell and Gardner, 2012, Omachonu, 2010). However the concept of quality of care, and specifically the definitions of quality patient care in the emergency department has produced considerable debate within the literature (Lowthian and Cameron, 2012, O'Connell and Gardner, 2012, Cameron et al., 2011). Previously, emergency department patient care was considered to be of varying quality and ill defined (Cameron et al., 2011). In November 2011, the International Federation for Emergency Medicine developed a framework to provide a platform to underpin the pursuit of quality and safety in all emergency departments. The framework lists domains of quality patient care that

encompass the delivery of safe, effective, patient-centred, timely, efficient and equitable health care to all patients (International Federation of Emergency Medicine, 2012). This review clearly demonstrates quality of care in emergency nurse practitioner services, is hard to define, ambiguous and not used routinely as a measure of the service effectiveness. Dinh et al.'s (2013) study was unique in that it incorporated three of the defined features of quality care as measures of service effectiveness; patient satisfaction, follow up health status and adverse effects. Other studies evaluating nurse practitioners have used accuracy of X-ray interpretation, unexpected patient returns, missed injury rates, inappropriate management of patients and unscheduled returns to emergency department as measures of quality of care when reviewing or comparing emergency nurse practitioner service (Nash et al., 2006, Colligan et al., 2011, Dinh et al., 2012, Lee et al., 2013).

Satisfaction with emergency nurse practitioner service is an important consideration in relation to service effectiveness. There appears to be a good body of evidence in favour of a significant impact of emergency nurse practitioner services on patient's satisfaction (Jennings et al., 2009, Dinh et al., 2012, Nash et al., 2006). Patients' are viewed as consumers of healthcare and there is a greater emphasis on ensuring that the patient's health care experience is valued (Muntlin et al., 2006). The majority of studies examining patients' satisfaction are single sites and consist of self-administered questionaries that patients complete following their emergency department encounter (McMullen et al., 2001, Roblin et al., 2004, Cooper et al., 2002, Byrne et al., 2000, Jennings et al., 2009). The review has demonstrated consistently a trend in favour of high levels of patients' satisfaction with emergency nurse practitioner services (Sandhu et al., 2009, Hoskins, 2011, Byrne et al., 2000, Mabrook and Dale, 1998). A common element from all studies is no reduction in patient satisfaction with emergency nurse practitioner service compared with medical service and anecdotally a greater holistic approach to discharge instructions and health education (Jennings et al., 2009, Nash et al., 2006, Dinh et al., 2012). Much of the literature shows that a patient's satisfaction is closely linked

Waiting times for care to be delivered in the emergency department is a key performance indicator of service efficiency used throughout contemporary emergency settings. Significantly increasing waiting times can have impacts on patient care with increased adverse events, mortality and hospital length of stay (Forero et al., 2010). Due to increasing service issues such as overcrowding, increased demand and the challenges of meeting time performance targets (National Health Performance Authority, 2013), emergency departments are focusing on the ability to deliver timely and efficient healthcare to patients. Emergency nurse practitioner services appear to have had significant impact on waiting times for patients to be assessed (Carter and Chochinov, 2007, Considine et al., 2010, Fry et al., 2011, Steiner et al., 2009, Van der Linden et al., 2010, Colligan et al., 2011, Jennings et al., 2008, Dinh et al., 2012), and consequently improved access for patients in several of these key performance targets. Recently implemented National Emergency Access Targets (NEAT) in Australia and elsewhere, have forced health services to re-evaluate their delivery of care and evaluate service models. Time-based performance targets such as waiting times are now utilised to compare and contrast health service efficiency.

Limitations

This current review provides a timely appraisal of the status of research evaluating the effectiveness of emergency nurse practitioner services. The ability to calculate a pooled effect of estimates on the impact of nurse practitioner services on cost, quality of care, satisfaction and waiting times would have been invalid for a number of reasons. There are many potential confounders in the studies reported and hence due to the heterogeneity of the available research only a narrative synthesis of the results could be included. This review was impeded by the paucity of available research that examined the effectiveness on emergency nurse practitioner service on key outcome measures such as cost, quality of care, satisfaction and waiting times. Since 2006 there has been limited enquiry into an expanding emergency nurse practitioner service and the impact on safety and quality of patient care. The major limitation in all of the studies in the review includes the varied definitions used to define and describe the role of the emergency nurse practitioner. None of the studies provided stable operational definition for emergency nurse practitioners. The lack of operational definition for emergency nurse

practitioners to differentiate the service from other advanced practice nursing roles leads to considerable international confusion and prohibits cross border comparisons. The variability of the clinical skills and theoretical knowledge for the nurses participating in the above studies is a significant limitation.

Any additional clinical workforce added to an emergency department model of care can often be linked to reduction in waiting times, due to the nature of an extra practitioner. This factor was not controlled for in any of the review studies. The implementation of emergency nurse practitioner services and whether they have evolved from nurse or medical substitution results from local needs. Nevertheless any innovation in emergency department service delivery that impacts patient quality of care needs to be examined.

Conclusion

Not-with-standing the above limitations, the narrative findings from this systematic review suggest that emergency nurse practitioner services do impact patient satisfaction and waiting times positively. Cost effectiveness of emergency nurse practitioner service was shown to be equal to that of other health professionals in regards to soft tissue management and overall quality of care was higher within emergency nurse practitioner service. However the impact of the emergency nurse practitioner service on emergency department patient care delivery needs to be evaluated by robust research to produce evidence that informs healthcare policy and service developments. This will in turn provide context for further studies and provide an evidence base for healthcare leaders to ensure sustainability and ongoing service reform models.

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2.6 Summary

Australian research on E-NP service effectiveness is scant and lacking rigour. This systematic review has established that there is a paucity of research in the form of RCTs and good quality observational studies. It is difficult to make comparison with the evidence presented due to operational differences such as standardised definitions of NPs, funding models of ED workforce, and the quality of the research conducted. The rapid uptake of E-NP services has outpaced attempts to study the effectiveness of this service innovation. Evaluating workforce reform and key strategies for ED care of patients is paramount for healthcare leaders, policy makers and service providers. The systematic review has shown the need for contemporary research into E-NP service that is well powered and designed to test a health service innovation.

Chapter 3. Background and preparatory work

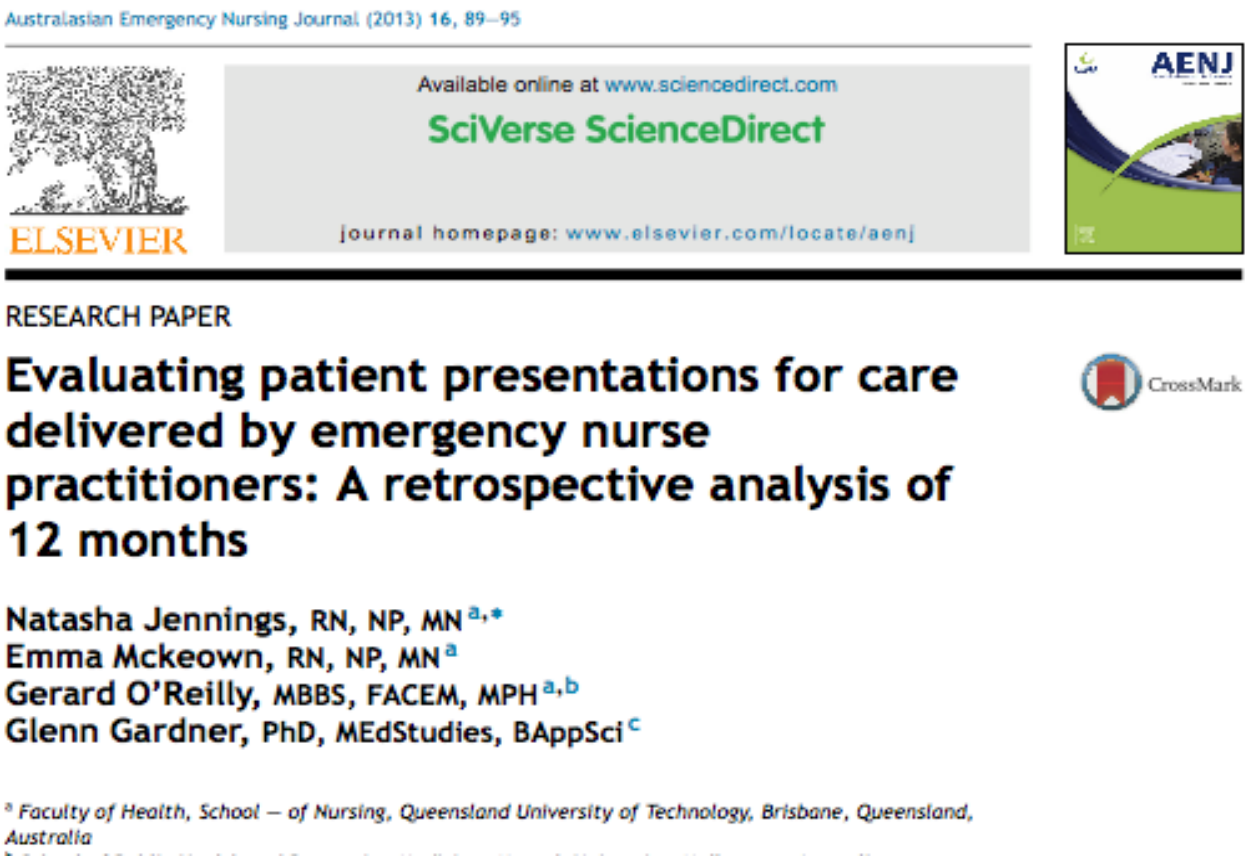
3.1 Introduction

The published systematic review (Jennings et al, 2014), has highlighted that there is a paucity of research in the form of RCTs and good quality observational studies exploring E-NP service effectiveness. The literature suggests the use of a RCT to evaluate measures of effectiveness for complex interventions such as E-NP service, in order to inform decisions about overall effectiveness of an intervention. Conducting a well-powered, prospective, randomised controlled study with a pre- planned frame for statistical analysis is considered the best approach for any interventional clinical study (The Joanna Briggs Institute, 2014, Grossman and Mackenzie, 2005). These considerations were taken into account in view of the complexity of E-NP service interventions and the need to measure effectiveness at different levels of health care.

Specific preparatory work was required for this research to gather a sound foundation upon which to design the protocol of the RCT to investigate the clinical and service effectiveness of E-NP service. The preliminary research reported in this chapter was conducted to establish baseline characteristics of the patient cohort serviced by E-NPs to inform decisions about the hypotheses to be generated to address the thesis aims. The body of work presented in this chapter was essential to ensure the RCT was well designed and built upon contemporary data and to support careful planning.

This preparatory work has two distinct and important components that provided a robust platform for the main study. Study 1 was an audit evaluating patient presentations for care delivered by E-NPs. Study 2 was the pilot study used to test the variables that would be used for the primary data analysis for the pragmatic RCT.

3.2 Publication 2 - Study 1 – E-NP service audit



Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective analysis.

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3.2.1 Introduction

In setting the foundation to develop a protocol and the methodology for the RCT, an audit of E-NP service was undertaken. The aims of this review were to:

1. Examine the demographics of the patient population
2. Evaluate ED quality indicators for this cohort, specifically:
    - Waiting time
    - Overall length of stay in emergency department
3. Evaluate patient characteristics
    - Discharge diagnosis
    - Referral patterns

All patients presenting to the designated ED site and managed by E-NPs from January 01 2011 to December 31 2011 were included in the review. Data collection included baseline demographics, waiting times to be seen, overall length of stay, ED discharge diagnoses and the type of practitioner the patient was referred to. Data were extracted and imported directly from the ED Patient Information Research Ethics Committee in August 2012, approval number 361/12 (Appendix A) and Queensland University of Technology Human Research Ethics Committee. Study 1 was completed in December 2012 and the manuscript was accepted for publication in May 2013.

3.2.2 Contribution of authors

This manuscript presents the audit of E-NP managed patients over a 12-month period at the RCT study setting. This review was lead by myself under the supervision and guidance of my primary supervisor Professor Glenn Gardner and associate supervisor Dr Gerard O'Reilly. The author team was: N Jennings, E. McKeown, G O'Reilly and G Gardner. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship that includes: substantial contribution to the conception of the review; the acquisition, analysis and interpretation of data for the audit; AND Drafting the work or revising it critically for important

intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (ICMJE, 2014).

3.2.3 Published manuscript

Title

Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective analysis.

Abstract

Background: The delivery of quality patient care in the emergency department (ED) is emerging as one of the most important service indicators to be measured in health services today. The emergency nurse practitioner role was implemented as a service innovation in one Melbourne ED, Australia, in July 2004. The primary aim of the role was intended to enhance healthcare services, improve the efficiency and timely delivery of high quality care to patients.

Aim: To conduct a retrospective study of patient presentations at the ED to obtain a profile of the characteristics of patients managed by emergency nurse practitioners. Specifically the objectives of the study were to:

1) examine the demographics of the patient population
2) evaluate data on emergency department service indicators for this patient cohort

Method**:** A descriptive exploratory design was used. All patients presenting to the ED from January 01 2011 to December 31 2011 and managed by emergency nurse practitioners were included in the review. Data collection included baseline demographics, waiting times to be seen, length of stay, ED discharge diagnoses and referral patterns. Data were extracted and imported directly from the ED Patient Information System (Cerner log), for the specified time frame.

Results**:** A total of 5212 patients were reviewed in the study period. The median age of patients was 35 years and 61% of patients were male. The most common discharge diagnosis was *open wounds to hand/wrist*. Waiting times to be seen by the emergency nurse practitioner were 14 minutes and lengths of stay for patients with a discharge disposition of home were 122 minutes.

Conclusions**:** This study has provided information on patient baseline characteristics and performance on important service indicators for this patient sample that will inform further research to evaluate specific outcomes of the emergency nurse practitioner service.

Key Words

Emergency nurse practitioner, quality of care, fast track, emergency department

Main text of manuscript

Introduction

Emergency Departments (ED) have seen more than 7% growth in patient presentations over the last 5 years and this has contributed to an ever-growing burden on the delivery of quality patient care[1]. The capacity of EDs to consistently deliver timely, high quality patient care is impacted by the increase in the number and complexity of presentations. The increasing incidences of chronic disease in the community, reduced access to primary healthcare and fewer general practitioners have contributed to increased demand in ED services [2,3,4].

The delivery of quality patient care in the ED is emerging as one of the most important service indicators to be measured in health services today. The Emergency nurse practitioner (E-NP) model is the fastest growing NP model nationally with a 61% increase in the last three years [5]. Emergency nurse practitioners have been viewed as one potential solution to address this increased demand and overcrowding in the ED and have been employed to improve service indicators such as access and efficiency, directly impacting on quality patient care [6, 7, 8].

A framework for measuring quality patient care in the ED was developed in 2011[9]. The framework was formulated due to concerns that ED medical care was of varying quality and ill defined. The framework listed eight domains of quality patient care. The domains were defined as safe, effective, patient centered, timely, efficient and equitable health care to all patients. This concept has produced considerable debate within the literature [1,8,9], around the constructs of quality patient care in the ED. A universally accepted definition of quality patient care is not

available as the notion is considered multi-faceted and complex [10]. Hence for the purposes of this review the domain referring to timely patient care will be examined. Patients, clinicians, administrators and policy makers use time performance indicators as a measure of service effectiveness and efficiency. Although, there is limited evidence on the effectiveness of E-NP on ED service outcomes and the quality of patient care. Therefore the purpose of this research is to evaluate E-NP service indicators as a measure of quality patient care. This descriptive exploratory review will:

1. Examine the demographic and clinical characteristics of the patient population
2. Evaluate ED service indicators for this cohort including:
    - Waiting time
    - Overall length of stay in the emergency department for both admitted and discharged patients
    - Disposition diagnosis and destination

Design

A descriptive exploratory design utilising a sampling frame of 12 months from 1st January 2011 to 31st December 2011 was used. All patients managed by the E-NPs during the study period were included in the review.

Sample/participants

The study was conducted in an Emergency Department (ED) in Melbourne, Australia. The ED is an urban, adult tertiary department with an annual ED census in 2011 of over 56,000 patients.

The ED model of care is serviced by a traditional medical service with treatment decisions carried out by medical practitioners. This model also incorporates the provision of E-NP services. Emergency nurse practitioners are a hybrid service delivery model, holding both nursing and medical skills with an emphasis on health promotion, education and holistic care [6]. The E-NP model of care specifically includes assessment and management of patients using critical decision-making skills, referring directly to other health care providers, prescribing medications, performing interventions and ordering and interpreting diagnostic investigations. Emergency nurse practitioners' work both independently in managing patients and collaboratively within the ED model of care. Emergency nurse practitioners are well established in this setting since their inception in 2004 with eight E-NPs providing seven days a week service from 0700-2330pm. The Emergency nurse practitioner staffing profile during the study period included two fulltime E-NP, two part time E-NP candidates, two E-NPs on maternity leave and 2 part time E-NP's. The effective full time hours employed at the site was a total of five. Emergency nurse practitioners' individual patient workloads on average are 8-10 patients per shift. Dependent upon the breadth of experience or whether the E-NP is undertaking their candidate training program often impacts the numbers of patients seen. The Emergency nurse practitioner service also includes collaborative practice, so in fact the E-NP may have signed on and treated for example eight patients on their shift but they may have also contributed care to patients in trauma and resuscitation for a proportion of their shift time. The Emergency nurse practitioner service is geographically located in the fast track area of the ED. Fast track services enhance ED care processes in an area designated for timely assessment, treatment and discharge of patients seeking primary care type services for less serious illnesses and injuries [11,12]. The Emergency nurse practitioner focuses on the management of patient presentations within specific inclusion

criteria. Patient presentations managed include cellulitis, open wounds, limb injuries, abdominal or back pains and other minor presentations.

Inclusion criteria

This study was a retrospective review of all patients managed by E-NPs at the study site during the sampling time frame. All study patients must have presented to the ED between the hours of 07:00 and 23:00 hours when E-NP service was available. Patients whose disposition diagnosis was determined as “left after clinical advice” or “left at own risk” were excluded from the study, as they were not managed by the E-NP service and left the ED without any clinical management.

Data Collection

All review data were entered on the ED patient information system (Cerner Log), a patient attendance registry that has been used at the site for 14 years. The log is a computerized system that collects surnames of individual practitioners that manage ED patient care.

Ethical considerations

The study was approved by the Hospital Research Ethics committee as a low risk project in June 2012.

Data analysis

The ED service indicators examined included waiting and length of stay (LOS) times for patients managed by E-NPs. Waiting time was defined as time in minutes from initial registration until treatment commencement by the E-NP. Length of stay was defined as the time in minutes the patient spent in the ED from initial registration until time of disposition from the ED. The Victorian Department of Health Services mandated emergency department LOS targets until the end of the calendar year of 2011. Compliance with the 4 hour ED LOS for at least 80% of non-admitted patients was anticipated. Currently, the proportion of non-admitted patients with a length of stay under four hours nationally in major metropolitan hospitals is 54 per cent [13].

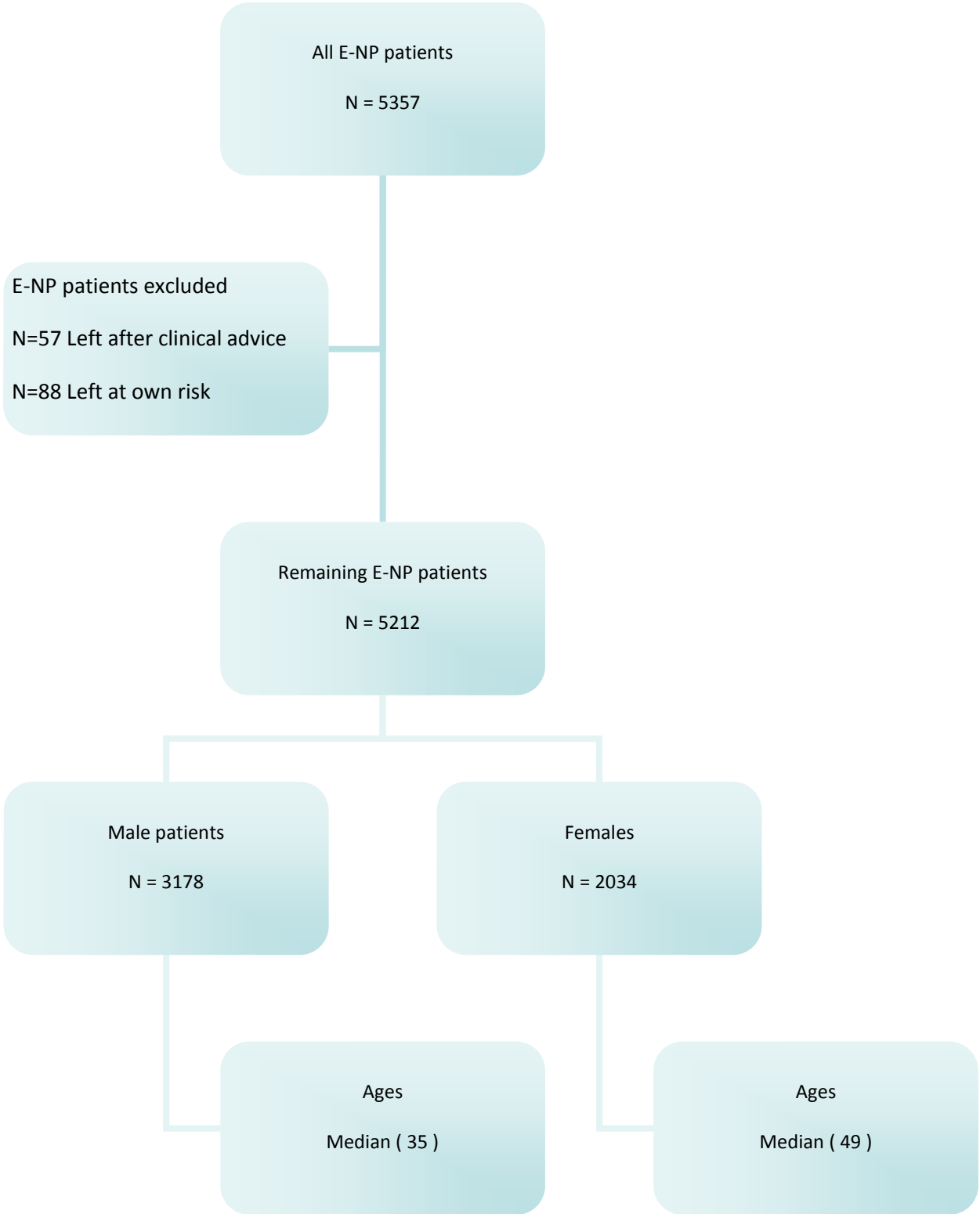
Disposition was defined as the final destination of the patient's acute care episode. A disposition diagnosis was based upon the common diagnostic subgroup classifications of ICD-10-AM (Statistical classification of Diseases and Related Health Problems, 10th Revision, Australian Modification). All patients were de-identified prior to data analysis. Descriptive statistics were used to summarise the profiles of ED presentations for E-NP managed care. Data were analysed using Stata (StataCorp, College Station, TX, USA). Data were not normally distributed so medians and interquartile ranges (IQR) ranges are presented for analysis.

Results

A total of 5,357 patients were managed by E-NPs between January 01, 2011 and December 31, 2011. One hundred and forty five patients were excluded from the analysis as their disposition

diagnosis included “left after clinical advice” or “Left at own risk” (see Table 1). The median age of patients was 35 years (n= 5212) and 61% of patients were male

Table 1. Included patients



The most common patient presentations managed by the E-NP service were open wounds to wrist or hand (n= 547). The next most common presentations included fracture of and unspecified parts of the wrist and hand (n=292), Surgical follow-up care unspecified (n=244) and sprain/strain of ankle unspecified (n=202), respectively. A list of the top 10 ICD discharge diagnoses is provided as Table 2. In total there were 359 different discharge diagnoses described by the E-NP service model.

Table 2- Top 10 patient presentations by ICD codes

Ranking	N=	ICD code	Descriptors
1	547	S619	Open wound of wrist and hand part, part unspecified
2	292	S628	Fracture of other and unspecified parts of wrist and hand
3	244	Z489	Surgical follow-up care, unspecified
4	202	S9340	Sprain and strain of ankle, part unspecified
5	178	L039	Cellulitis, unspecified
6	144	S0188	Open wound of other parts of head
7	136	Z209	Contact with and exposure to unspecified communicable disease
8	109	S929	Fracture of foot, unspecified
9	101	Z099	Follow-up examination after unspecified treatment for other conditions
10	99	S936	Sprain and strain of other and unspecified parts of foot
TOTAL	2052	359	

Median waiting times to be seen by the E-NP was 14 minutes (IQR 7-33) and length of stay for patients with a discharge disposition of home was 122 minutes (IQR 77-177). Those patients whom discharge disposition was admission/other, their length of stay was 271 minutes (IQR 190-405) (see Table 3). Overall, 95.9% of the discharged home group (n= 4509) left the ED within the 4-hour service target.

Table 3- Waiting times and length of stay

Service Indicators	E-NP service (minutes)
Waiting times	14 (IQR 7-33)
Length of stay	131 (IQR 82-200)

The most common discharge disposition were home (n= 4509). The next most common discharge disposition were ward (n= 355) and short stay unit (n= 252) (see Table 4). Patients were most commonly referred to their Local Medical Officer (n=85%).

Table 4- Disposition

Disposition	N=	%
Home	4509	86.5
Left at own risk after treatment started	25	0.5
Short Stay Unit Admit	252	4.8
Theatre	47	0.9
Ward Admit	355	6.8
Other	24	0.5
Total =	5212	100

Discussion

The purpose of this study was to profile the characteristics of patients managed by E-NPs and to evaluate specific service indicators as a measure of quality patient care. This review is timely as part of the National Health Reform agenda will see the roll out of the new National Access Target for Emergency Departments, known as the 'National Emergency Access Target' ('NEAT') in 2012. The NEAT is measured as the percentage of patients who leave the ED within 4 hours of their arrival. The time is measured from when the patient arrives at the ED to the time the patient has been discharged to either admission to a ward, transferred to another hospital, or goes home. The initial compliance target for 2012 is mandated at 72% with expectations of that figure gradually increasing to 90% by the year 2015 [14]. During the sampling time frame the Victorian Department of Health Services had mandated targets for time target compliances and NEAT did not come into effect until after the study period.

Health services today are focusing on quality of patient care in the ED and the ability to deliver timely and efficient healthcare to all patents. The recently implemented NEAT targets applied in 2012 have forced health services to re-evaluate their delivery of care and evaluate their service models. Time based performance targets such as wait times and LOS measures are utilized nationally to compare and contrast health service efficiency. In this review large numbers of patients were managed by the E-NP service with the NEAT target, with the most common discharge diagnosis of open wounds to wrist or hand and fractures to the wrist or hand.

Demographics

The median ages of patients managed by E-NPs were 35 years with 61% were male. Considering E-NP services tend to be based in lower acuity areas and manage large numbers of minor injuries, the median age and gender profile was consistent with other published studies [15]. Typically males in there thirties make up the majority of the population performing laboring and working with machinery occupations. These high-risk occupations are considered to sustain more injuries requiring presentations to the ED for management. The resultant care is managed by the E-NP services. In the Australian context of studies undertaken in EDs and fast tracks, males were more than 55% of the population with median ages of around 30 years [12,16,17,18,]. In the UK, males were also identified as the majority of presentations managed by E-NP services [19,20]and one randomized controlled trial of nurse practitioner services [21], saw males contributing the majority of patients at 58% and the median age of 37 years.

Wait times

Emergency nurse practitioner services are generally focused on patient presentations within Australasian Triage Scale (ATS) categories 2-5[22]. The ATS is designed for use in hospital based emergency services throughout Australia and New Zealand. The ATS scale is utilized for rating clinical urgency and attempts to ensure patients are seen in a timely manner commensurate with their medical urgency. Emergency nurse practitioner patients therefore can wait from 10 minutes to 120 minutes for treatment in the ED. The median wait time for patients managed by E-NPs was 14 minutes (IQR 7-33) and all patients in this study were seen within the 120 minutes time frame. Although wait times were not stratified according to ATS categories it is anticipated if waiting times were delayed this would have a negative impact on the service indicator of length

of stay. In this study length of stay was very favourable and not affected by any measures of wait times. The median waiting time for FastTrack patients was 50 minutes (IQR 23-96). Another similar local urban ED[23,] saw nurse practitioners proportion of patients seen within ATS recommendations reaching levels of 82.5%. Other Australian results for waiting times range from median of 13 minutes (IQR 6-28)[18,24,] and in New Zealand[14] 14 minutes (IQR 5-27).

Length of stay

The median LOS managed by E-NPs was 131 min (IQR 82-200) for those patients in the study whose discharge disposition was 'home'. Comparisons of LOS can be made with the literature at both an Australian and international context. One Australian transitional E-NP models median LOS was 109 minutes[18], and in the New Zealand setting [19] E-NP LOS was 117 minutes, and other local models E-NP LOS was 102 minutes[23, 24], which utilise the same definition for LOS outcomes. International comparisons of E-NP LOS include 102 minutes[20,25] from Ireland and the United Kingdom with E-NP LOS 83 minutes. ED LOS compliance with the 4 hours non-admitted patient target in this study was 95.1 %, very consistent with local results[17] showing a compliance of 95.9%.

Presentation types

In the study setting E-NP services were located geographically in fast track and managed patients within a defined scope of practice. The aim of the fast track service is to provide an efficient and effective way of caring for patients who present to the ED with minor illnesses and injuries. There is strong evidence to suggest that fast track services streamline the management of patients

impacting favourably upon patient outcomes[26,27]. Fast track patients can be directly managed rapidly and do not require intensive concentrated ED care. The most common presenting discharge diagnoses were closely related to open wounds (hand/wrist), sprains/strains (foot/ankle/hand/wrist) and fractures (hand/wrist). Other Australian E-NP studies[18,23] have also consistently concentrated on musculoskeletal/soft tissue group with the most common diagnoses of open wound (hand/wrist) and fracture (hand/wrist).

Referral patterns

The cohort of patients seen by E-NPs most often require follow up and re assessment of their antibiotics compliance and safety, dressings, and follow up of results. Therefore the most common referrals made by E-NPs were to the local medical officer. The organization training for the E-NP service requires the practitioner to provide material and resources for all patients being discharged home to their local medical officer. Previous research has demonstrated patients receive more health information and better discharge instructions when compared with traditional care[29,29,30].

Emergency nurse practitioners are a hybrid service delivery model, holding both nursing and medical skills with an emphasis on health promotion, education and holistic care. The challenge facing health services today is to provide quality of care to ED patients while balancing the complex need for increased demand of services. Emergency nurse practitioners are one potential innovation to address this need. Research has shown that this service innovation has been rapidly

adopted in Australia and internationally but there is scant information to date on the pattern of service and the influence on safety and quality of patient care.

Limitations

This study drew upon a large database to describe the demographic and clinical features of a cohort of patients whose ED presentation was managed by E-NP service. However, consideration of these study findings needs to take into account some limitations in the study design. With a retrospective study design, there is the likelihood that some of the data collection was incomplete and inaccurate. Furthermore we limited the variables to those where data was most likely to be complete; other unmeasured variables may have contributed to a more comprehensive evaluation of waiting times and length of stay. The study was conducted at a single site with a well-established E-NP service. Hence the utility of the study's findings is limited to service contexts with similar characteristics. The study does however provide a substantial baseline dataset to inform subsequent prospective research into the clinical efficacy and service effectiveness of the E-NP service innovation

Conclusions

This research into E-NP service has illustrated that patient care is delivered to a large number of patients with consistent demography as interpreted from the existing literature. It has provided baseline characteristics and results on service indicators that will inform further research to evaluate specific outcomes of the E-NP service and quality of patient care.

Note: 5212 patients included in the review referred to patient presenatations.

Author contributions

NJ, GG conceived and designed the study. NJ, EM developed the study protocol and supervised data collection. NJ, EM, GO, and GG analysed the data. All authors contributed and approved the manuscript.

Provenance and conflict of interest

There is no conflict of interest.

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3.3 Publication 3 – Pilot Study – Time to analgesia pilot study

Time to analgesia for care delivered by nurse practitioners in the emergency department

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3.3.1 Introduction

The systematic review informed the decision to focus on clinical outcomes in relation to E-NP service effectiveness. I had anticipated and hypothesised the clinical outcomes for my RCT to be based around end points associated with effectiveness of timely analgesia delivered by the E-NP service. These outcomes needed to be carefully selected and defined to align with the research aims. The primary outcome must inherently provide the most clinically relevant evidence related to the aim of the study and reflect the accepted standards in the health services research (Akobeng, 2005). Therefore it was imperative to conduct a pilot study to test these variables and to assist with the sample size calculation and strategies for primary data analysis for the RCT.

The objectives of this component of the research were to evaluate time to analgesia administered to patients presenting with pain and managed by the E-NP service. Describing the documentation of frequency of pain scores was a secondary objective. A single investigator conducted a retrospective, explicit chart review. All patients presenting with a primary complaint of pain and managed in the fast track area by the E-NP service were eligible for inclusion. A sample of 128 consecutive patients presenting prior to 18 December 2013 were included in the study. Time to analgesia from presentation to the ED was the primary outcome measure. Time to analgesia after assessment by the E-NP service was the secondary outcome. Ethics permission was granted by the Alfred Research and Ethics Committee in December 2013, approval number 361/12 (Appendix B) and Queensland University of Technology Research and Ethics. Study 2 was completed in February 2014 and the manuscript was accepted for publication in July 2014.

3.3.2 Contribution of authors

This manuscript presents the time to analgesia for care delivered by nurse practitioners in the emergency department audit. This review was led by myself under the supervision and guidance of my primary supervisor Professor Glenn Gardner and associate supervisor Dr Gerard O'Reilly. The author team was: N Jennings, A Kansal, G O'Reilly, B Mitra and G Gardner. I mentored and liaised directly with the research assistant A Kansal, a final year medical student, with an interest in research. I also performed verification of entry on 20% of all the data forms. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship

that includes: substantial contribution to the conception of the review; the acquisition, analysis and interpretation of data for the audit; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (ICMJE, 2014).

3.3.3 Published manuscript

Title

Time to analgesia for care delivered by nurse practitioners in the emergency department- a retrospective chart audit

Abstract

Objectives. To evaluate quality of care delivered to patients presenting to the emergency department (ED) with pain and managed by emergency nurse practitioners by measuring:

1) Evaluate time to analgesia from initial presentation

2) Evaluate time from being seen to next analgesia

3) Pain score documentation

Background. The delivery of quality care in the emergency department (ED) is emerging as one of the most important service indicators being measured by health services. Emergency nurse

practitioner services are designed to improve timely, quality care for patients. One of the goals of quality emergency care is the timely and effective delivery of analgesia for patients. Timely analgesia is an important indicator of ED service performance.

Methods. A retrospective explicit chart review of 128 consecutive patients with pain and managed by emergency nurse practitioners was conducted. Data collected included demographics, presenting complaint, pain scores, and time to first dose of analgesia. Patients were identified from the ED Patient Information System (Cerner log) and data were extracted from electronic medical records

Results. Pain scores were documented in 67 (52.3%; 95% CI: 43.3-61.2) patients. The median time to analgesia from presentation was 60.5 (IQR 30-87) minutes, with 34 (26.6%; 95% CI: 19.1-35.1) patients receiving analgesia within 30 minutes of presentation to hospital. There were 22 (17.2%; 95% CI: 11.1-24.9) patients who received analgesia prior to assessment by a nurse practitioner. Among patients that received analgesia after assessment by a nurse practitioner, the median time to analgesia after assessment was 25 (IQR 12-50) minutes, with 65 (61.3%; 95% CI: 51.4-70.6) patients receiving analgesia within 30 minutes of assessment.

Conclusions. The majority of patients assessed by nurse practitioners received analgesia within 30 minutes after assessment. However, opportunities for substantial improvement in such times along with documentation of pain scores were identified and will be targeted in future research.

Keywords: nurse practitioners, emergency service, pain, analgesics, clinical audit

Main text of manuscript

Introduction

Acute pain is the most common reason for patients presenting to Australian emergency departments (EDs) (Kelly and Gunn, 2008, Holdgate et al., 2010, Doherty et al., 2013, Finn et al., 2012), and time to analgesia and documentation of pain scores are key clinical indicators compiled by the Australian Council of Healthcare Standards. However, timely delivery of effective analgesia remains an ongoing challenge and the capacity of EDs to consistently deliver timely, analgesia may be impacted by the increase in the number and complexity of presentations. ED overcrowding, access block, the growing number of chronic diseases in the community and reduced access to primary healthcare have all contributed to this increased demand for services (Lowthian and Cameron, 2012, Lowthian et al., 2011, Forero et al., 2010, Health Workforce Australia, 2012).

One of the goals of providing high quality emergency care is the timely and effective delivery of analgesia for patients. In a joint position statement released by the Australasian College for Emergency Medicine, and the College of Emergency Nursing Australasia, pain management is identified as a fundamental component of quality care for ED patients(Australian College of Emergency Medicine, 2009). Early and effective pain management in the ED setting may also

play a pivotal role in reducing the likelihood of chronic pain syndromes, pain-related anxiety and distress following an acute pain presentation (Thomas and Shewakramani, 2008, Turturro, 2002, Weisman et al., 1998). A median time to analgesia following a presentation to the ED of 30 minutes is considered the national standard, but in practice, has been shown to be over an hour (Herd et al., 2009). Poor documentation of pain scores has been consistently demonstrated (Furyk and Sumner, 2008, Wood, 2008, National Health and Medical Research Council, 2012).

Nurse practitioners in the ED are a rapidly expanding service model within Australia (Middleton et al., 2011, Gardner et al., 2010, Jennings et al., 2013), however there has been limited robust evaluation on their impact upon quality of patient care and clinical outcomes. In previous studies describing analgesia prescribing practices among Australian nurse practitioners (NP), there has been no analysis of pain management or the timeliness or effectiveness of analgesic prescribing (Dunn et al., 2010, Buckley et al., 2013).

The primary aim of the study was to evaluate time to analgesia administered to patients presenting with pain and managed by a NP. The secondary aim of this study was to determine the frequency of pain scores being documented.

Methods

Setting: In Australia, a framework delineates EDs into four levels that reflect increasing capacity and capability to provide emergency care, support, education and research to the overall health

care system (Australian College of Emergency Medicine, 2012b). The Alfred Hospital is serviced by a level four ED, namely a large multifunctioning major tertiary referral hospital with capabilities for managing a wide range of complex conditions. The EDs annual attendance was approximately 55,000 patients in the last fiscal year. The ED is serviced by a 'Fast Track' area, staffed by nine NPs between the hours of 0700-2330, seven days a week. The NPs deliver a hybrid service delivery model, holding both nursing and medical skills and geographically located in the fast track zone. Specifically the NP model of care includes assessment and management of patients both independently and collaboratively within the established ED model of care. Patients deemed suitable are directed to the fast track area by a streaming nurse. All streaming nurses hold post graduate qualifications in emergency care and are considered very experienced and senior nurses in the ED. The streaming nurses' decision of where to allocate patients is protocol driven based on patients' presenting complaints. There are no nurse initiated analgesic protocols in place currently in the ED. Occasionally the streaming nurse if time permits may seek an authorised person to 'write up' analgesia while the patient waits to be taken through to their treatment zone.

Design: A retrospective, explicit chart review was conducted by a single investigator. A detailed data collection form was designed to allow for information to be easily coded into a suitable format for data entry and statistical analysis. A coding manual was produced for verification and transparency. To ensure the highest accuracy of our data collection by the single investigator, 20 % of all data forms were randomly selected by the primary investigator to compare the entered data with the hard copy and the ED patient information System (Cerner- Firstnet^{TM}) output. All patients were assessed by the streaming nurse to allocate a patient's urgency for care and

treatment zone allocation. The streaming nurse documents a patient's complaint of pain as a mandatory component of their assessment. All patients presenting with a primary complaint of 'pain' and managed in the fast track area by a NP were eligible for inclusion. Patients who did not receive analgesia during their presentation were excluded. Time of registration into the ED patient information system (usually entered by the registration clerk on arrival) was used as the arrival time. Documentation of pain scores and time of analgesia administration was extracted from the medication chart in the patients' electronic medical records.

All consecutive patients from the time-period of 18 December 2013 and retrospective as far as required to comply with the required sample size were eligible for inclusion. Patients with data missing for any of the stipulated times or diagnosis were handled by list-wise deletion. Time to analgesia from presentation to the ED was the primary outcome measure. Time to analgesia after assessment by a nurse practitioner was the secondary outcome measure.

Analysis: For an absolute (risk) difference between the hypothesized proportion (analgesia given by 30 minutes) and the proportion in the study population (alpha=0.05 and power=0.9) of 20%, the most conservative (largest) sample size needed was 64. To allow a subgroup analysis of the association between pain score documentation and time to analgesia, the sample size was doubled to 128. Data were stored in Microsoft Excel and analysed using Stata v 12.0 (College Station, Texas). Normally distributed continuous variables were reported as means (standard deviation) and ordinal or skewed variables were reported as medians (inter-quartile range). The significance of difference between two proportions was calculated using the chi-square test. A p-

value of <0.05 was considered to be statistically significant. The study was approved by The Alfred Hospital Research & Ethics Committee.

Results

In accordance with the required sample size, there were 128 patients with complete data for the required variables included in the study. Patient demographics and presenting complaint, sub-grouped by pain score documentation are listed in Table 1.

Table 1. Demographics

Variable	Pain score documented (n=67)	Pain score not documented (n=61)
Age (years)	36.6 (15.4)	34.8 (15.1)
Male sex (%)	37 (55.2%)	34 (55.7%)
Australasian Triage Scale category*		
2 (<10 mins)	0	1 (1.6%)
3 (<30 mins)	9 (13.4%)	4 (6.6%)
4 (<60 mins)	51 (76.1%)	46 (75.4%)
5 (<120 mins)	7 (10.4%)	10 (16.4%)
Initial pain score	6 (3-8)	-
Pain per body region		
- **Head**	2 (3.0%)	0
- **Face**	7 (10.4%)	5 (8.2%)
- **Upper extremity**	27 (40.3%)	25 (41.0%)
- **Thorax**	2 (3.0%)	1 (1.6%)
- **Abdomen**	3 (4.5%)	0
- **Back**	6 (8.9%)	2 (3.3%)
- **Lower extremity**	16 (23.9%)	22 (46.1%)
- **Multiple**	4 (6.0%)	6 (9.8%)

*ATS (Australasian Triage Scale) is designed for use in ED settings as a clinical tool for ensuring all patients are seen in a timely manner, commensurate with their clinical urgency. The assigned categories one (1) through to five (5) correspond to the time frame at which assessment and treatment should commence within the relevant waiting time from their arrival (Australian College of Emergency Medicine, 2012a)

The median time to be seen was 33.5 (12-60) minutes with 58 (45.3%) patients being seen within 30 minutes of presentation. The median time to analgesia from presentation was 60.5 (30-87) minutes, with 34 (26.6%) patients receiving analgesia within 30 minutes of presentation to hospital. There were 22 (17.2%; 95% CI: 11.1-24.9) patients who received analgesia prior to assessment by a nurse practitioner. Among the remaining patients that received analgesia after assessment by a nurse practitioner, the median time to analgesia after assessment was 25 (12-50) minutes, with 65 (61.3%) patients receiving analgesia within 30 minutes of assessment.

Among patients with pain score documented, 35 (52.2%) were assessed within 30 minutes, compared to 23 (37.7%) patients without documentation of pain score (p=0.10). There were 11 (16.4%) patients with documented pain scores who received analgesia within 30 minutes of presentation, compared to 23 (27.7%) patients without documented pain scores (p=0.007). When pain scores were documented and patients received analgesia post assessment, 36 (58.1%) patients who received analgesia within 30 minutes of assessment, compared to 29 (65.9%) patients who did not have pain score documented (p=0.42).

Discussion

This study has demonstrated a low frequency of pain scores being documented among the included sample. However, lack of documentation of pain scores did not appear to adversely affect analgesia administration times. Time to analgesia following presentation to hospital with pain was generally long, but after assessment by a nurse practitioner, the majority of patients received analgesia within recommended time-frames.

Time to analgesia from initial presentation

The national standard of 30 minutes between presentation to first analgesia is difficult to achieve in the ED setting where delayed access to care is not uncommon in the current health landscape (Huang et al., 2010, Asaro and Boxerman, 2007). There are numerous variables which impact upon the patients' journey to access definitive care. The time taken to register the patient demographics for basic registration, assessment by a streaming nurse, data entry into the ED patient information system, allocation of a treatment zone, time to travel to the zone and then the ability of a clinician being available to assess the patient. The critical measure of timely access to an ED is the time taken from patient presentation to be seen and begin treatment. Delayed access or access block has been associated with increased mortality, adverse events, time delays, patient and staff dissatisfaction and ambulance bypass (Lowthian and Cameron, 2012, Sprivulis et al., 2006, Cameron et al., 2009). In our sample where the median time to be seen was 32 minutes, timely management is difficult to deliver when assessment cannot start within the recommended period.

Our results are similar to previous reports. Among patients presenting with migraine, abdominal pain and fractured neck of femurs, time of presentation to first analgesia has been previously reported to be, 70-75 minutes (Holdgate et al., 2010, Herd et al., 2009).

In our study nurse practitioners demonstrated an ability to achieve the national target of analgesic administration within 30 minutes in >50 % of patients, but further investigation is required to

determine how to achieve greater efficiency in regards to timeliness of analgesia. Exploring the processes of 'writing up' the analgesic, accessing the pharmacy storage area, removing the analgesic, returning to the patient and administering the analgesics is indicated. A time mapping process used to determine inefficiencies will be explored in an attempt to reduce the time to analgesic measurement further. The nurse practitioner does work collaboratively with a registered nurse in the fast track zone and dependent upon numbers of patients, flow and acuity; this will determine if the nurse can access the analgesic for the nurse practitioner and reduce the time to analgesia. In effect this does happen anecdotally in some cases but often the nurse practitioner is managing a case load of patients and providing the sole care to these patients.

To our knowledge there has been no published studies evaluating an emergency NP service at delivering timely and effective analgesia. Registered nurse initiated analgesia in the ED has been reviewed before (Kelly and Gunn, 2008, Shill et al., 2012), and defined as the initiation of analgesia by nursing staff, using a pre defined protocol, prior to the patent being seen by a medical officer(Finn et al., 2012). Kelly, et al. (2005), reported that nurse initiated analgesia resulted in a significant decrease (26) minutes in median time to first analgesic dose and was also reported decreases in both times to first analgesia and pain scores (Fry and Fong, 2009). No nurse initiated analgesia protocol was available in our ED during the study period, but 22 patients received analgesia prior to assessment suggesting uncontrolled pain is easily identifiable at initial contact.

Documentation of pain assessment needs to be better to improve analgesia delivery in our EDs. Emergency department pain management practice relies on patients pain being evaluated on a

pain scale assessment tool (Holdgate et al., 2010) . Significant improvements in documentation of pain scores have been previously reported (Doherty et al., 2013), but needs to be sustained. Our results suggest that even in the setting of obvious uncontrolled pain when analgesia was administered prior to definitive assessment, the pain score was not documented in 23 cases. Such results suggest a lack of willingness or requirement for streaming nurses to document pain scores. Further education and awareness is required for the documentation of pain scores.

In this setting the streaming nurse is the first clinician that assesses all patients, and the model of care is not really adaptive to achieving the national target in its current format. The first clinician to assess the patient is ideally suited to implement a starting analgesic dose while the patient awaits definitive management and treatment. In our setting this practice is not currently protocol driven and hence requires the streaming nurse to leave their zone to access an authorised person to write up a first dose of analgesia. This practice is therefore not encouraged, severely compromising the ability of the streaming nurse to provide immediate advanced life support at the front entry to the ED if it's unattended. There are also no locked pharmacy storage facilities located at streaming, which also inhibits the ability of the nurse to access analgesics for timely administration.

Once pain assessment is documented by the streaming nurse, implementation of nurse-initiated protocols on initial treatment may enable shorter time to first analgesia in line with national benchmarking to improve quality of patient care. It is unlikely that such processes would add substantial time to the streaming process, and may enhance efficiency of analgesia delivery and

patient outcomes. A targeted education module for all ED staff, not just nurse practitioners, aimed at improving ED pain management to obtain best practice is warranted.

As a retrospective study, this analysis was dependent upon medical record documentation and ED information system extraction and therefore prone to misclassification or information bias. The study inclusion criteria required the streaming nurse to document 'pain as a presenting complaint', and there may have been some patients who did not complain of pain as their first complaint. These patients would therefore have not been captured in the sample but may have gone onto be managed by a NP and have analgesia administered. Selection bias was minimized through a liberal sample size estimation and selection of consecutive patients. Record extraction was performed by a single operator, but disagreements were unlikely as all data extracted were objective in nature and verification entry was performed at random on 20% of the sample. The study was performed in an adult ED serviced by a large number of NPs. Several limitations as described include, only one streaming nurse at a time, no access to protocols and drugs storage all inhibit the ability to meet this target efficiently. Time to analgesia from treating clinician is one aspect of quality care requiring evaluation until we can implement significant change to current practice. Generalisability of these results to other EDs with different patient census and staffing may be limited and requires further studies.

Conclusion

Timely and effective delivery of analgesia for patients presenting to the ED with pain is an important component of quality of care mandated by national clinical standards. Times to analgesia from initial presentation were long and consistent with the published evidence but require improvement. However, times to analgesia after assessment by a nurse practitioner were

substantially better. Opportunities for improvement in documentation and delivery of analgesia were identified and strategies for future research informed.

Author contributions

NJ, GO, BM and GG all contributed to the original concept and study design. AK collected all the data and NJ performed the verification entry. BM and GO conducted all the statistical analyses. NJ, BM and GO interpreted the results and prepared the manuscript. GG provided the final critique of the manuscript.

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3.4 Summary

The gold standard of clinical intervention studies is the application of an RCT. Previous E-NP service evaluations have failed to take into consideration the complexity of the service as an intervention. In order to evaluate the effectiveness of the E-NP model of care, an RCT study was designed. The preparatory work reported in this chapter provided the essential information for designing this pragmatic RCT. Each component of the preparatory work was carefully planned to enhance the reliability and validity of the main research.

The published article***, Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective analysis,*** describes study 1 of the research activity. The second published article, ***Time to analgesia for care delivered by nurse practitioners in the emergency department,*** was developed as a pilot study to inform the sample size and outcome measures for the main research. The following chapter reports the conceptual framework that was used to guide the study methodology and to frame research findings for the main research.

Chapter 4. Guiding methodology – a conceptual framework

A theory driven approach or conceptual framework is a necessary step to determine accurate and meaningful evaluations in HSR (Brazil et al., 2005). Considering the complexity of NP service as intervention a new approach to evaluation was required. A conceptual framework helps to guide researchers to a greater understanding of contextual factors that may influence effectiveness of an intervention (Brazil et al., 2005), and will, in turn strengthen and facilitate the utility of the research evidence into everyday practice.

4.1 Introduction

The Australian healthcare landscape is currently undergoing major health service reform (Council of Australian Governments, 2011). Engaging in health services reform requires embracing health services research (HSR) to conceptualise and focus on how different workforce models can achieve improvements in healthcare delivery and outcomes. The nature of this research requires a particular methodological approach taking into consideration 3 key elements:

- Health services research approach
- NPs as a service innovation
- Evaluation of complex interventions.

The methodological complexities of evaluating NP service relate to the nature of this service as an intervention that inherently has a number of interacting elements. Considering that E-NP service is already in place in the research environment and not amenable to manipulation, a different approach to evaluation was required. Such evaluation entailed a measured and well thought out approach to the research design and methodology. Learnings from a health services research approach (Black, 1997, Medical Research Council, 2000) were explored.

4.2 Health services research

Health services research evolved to provide unbiased, scientific evidence that will influence policy to impact health outcomes (Black, 1997). Health services research is fundamental in developing knowledge and evidence that can be translated into improvements in access and delivery of healthcare for all Australians. Health services research is both multidimensional and multidisciplinary and compliments the myriad of settings that are characteristic of the healthcare landscape. This research approach is operationalised across the continuum of health care and features include a focus on complex interventions, diverse methodologies, multidisciplinary approaches, policy focus and outcomes evaluated at a population level (Phillips et al., 2006).

Health services research is particularly relevant when it comes to measuring innovations in service delivery. A health services innovation is often defined as the introduction of a new model of care, service delivery or concept, aimed at improving quality of patient care (Omachonu, 2010). Nursing has developed and implemented unique models of care that are recognised as health service innovations, to optimise service delivery and improve patient outcomes (Rother and Lavizzo-Mourey, 2009). The NP is one such innovation and has been applied to a myriad of settings (Wilson et al., 2009, Wilson and Shifaza, 2008). The NP is a new type and level of health service that is not easily categorised. For example in the management of the ED patient with a fractured ankle, service is not uniform and easily delineated. The NP package of care inclusive of medical management is definable and easily recognised but it is other overarching professional practice elements that make an evaluation of the NP's interventions difficult. Some of the elements are: education and health promotion, written discharge instructions, general practitioner referral and patient preparedness for discharge. All these are elements make an important contribution to the effectiveness of the E-NP service and add value to the patient experience (Wilson et al., 2008, Considine et al., 2006, Sakr et al., 1999, Cooper et al., 2002). The NP model is distinctive in health service delivery as an innovation that operates from a nursing paradigm with the augmentation of medical and other health professional's skills. The NP model has a foundation grounded in nursing's values, knowledge, theories and practice but allows for independent and interdependent critical thinking and action (Jennings et al., 2008).

The evaluation and development of a health service innovation is highly complex and conventionally defined in research terms as simple or complex interventions with interacting components (Campbell et al., 2007). Simple interventions such as clinical treatments are typically new pharmacological therapies or devices. These clinical treatments can usually be rigorously tested with empirical evidence. Simple interventions comprise of either one or a few components that are usually fixed and have a low degree of contextual factors (Agency for healthcare research and quality, 2012). In contrast, complex interventions are often referred to as interventions that comprise of multiple components that may act both independently and interdependently (National Health and Medical Research Council, 2000). Complex interventions usually target multiple levels of behaviours and have a high degree of contextual factors. These elements can be behaviours of treating clinicians, model of care comparisons or therapeutics, and all aim at improving patient outcomes delivered at the level of patient or the health service. Therefore the NP service is a health service innovation that conforms with the definition of a complex intervention.

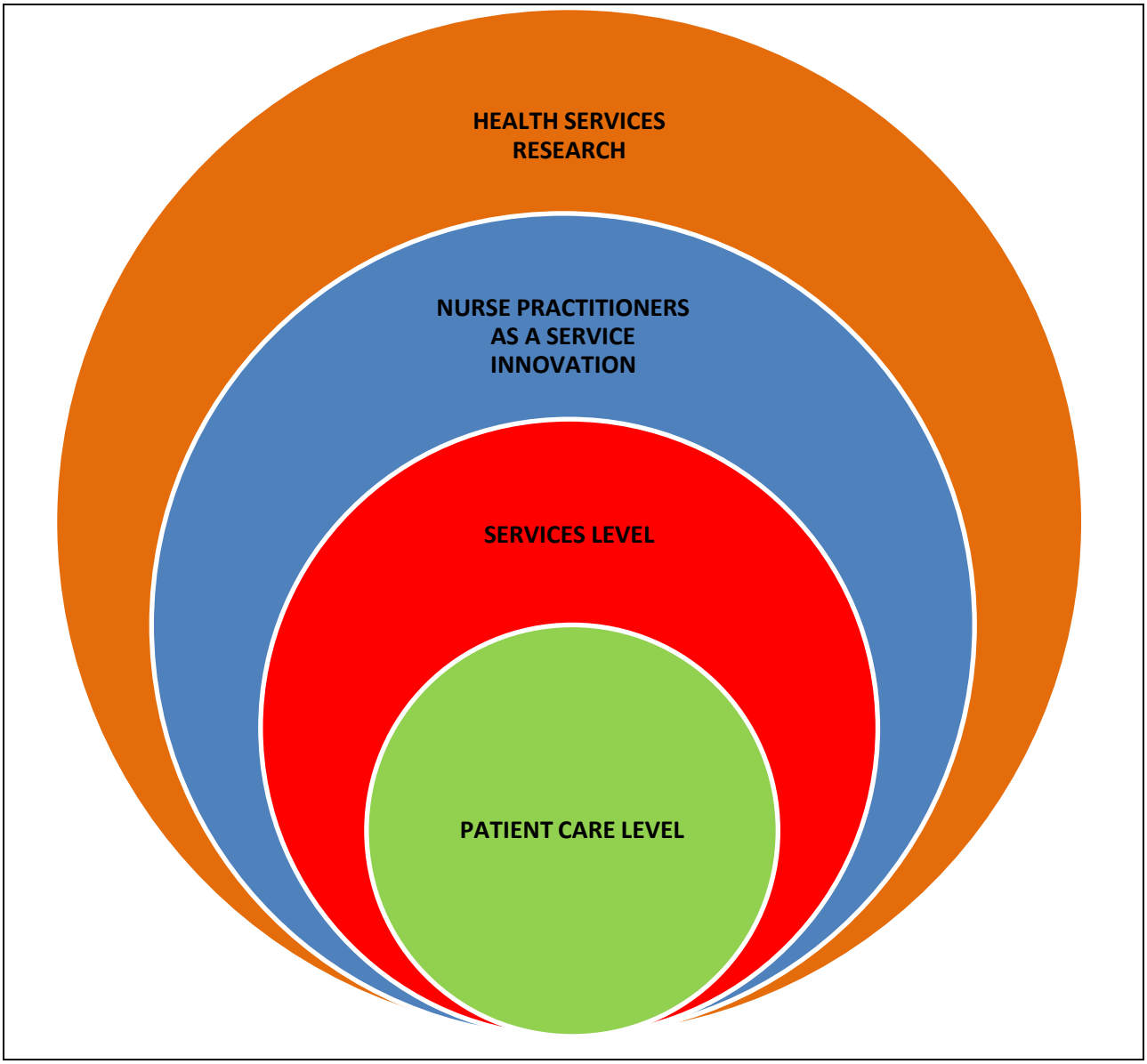


Figure 1- NP model as a service innovation

The above figure (Figure 1), demonstrates the relationship of the interaction between HSR and the NP model as a service innovation in health care reform. In order to evaluate the effectiveness of this intervention there is need for careful consideration of the multiple components and contextual factors that make up the NP service role. Hence, exploring the NP model as a complex intervention requires evaluation at a patient care level (complex individual intervention) and at a services level (complex services intervention). Using the HSR paradigm to incorporate a complex intervention inquiry for the NP model requires the development of a methodological approach to evaluate E-NP service.

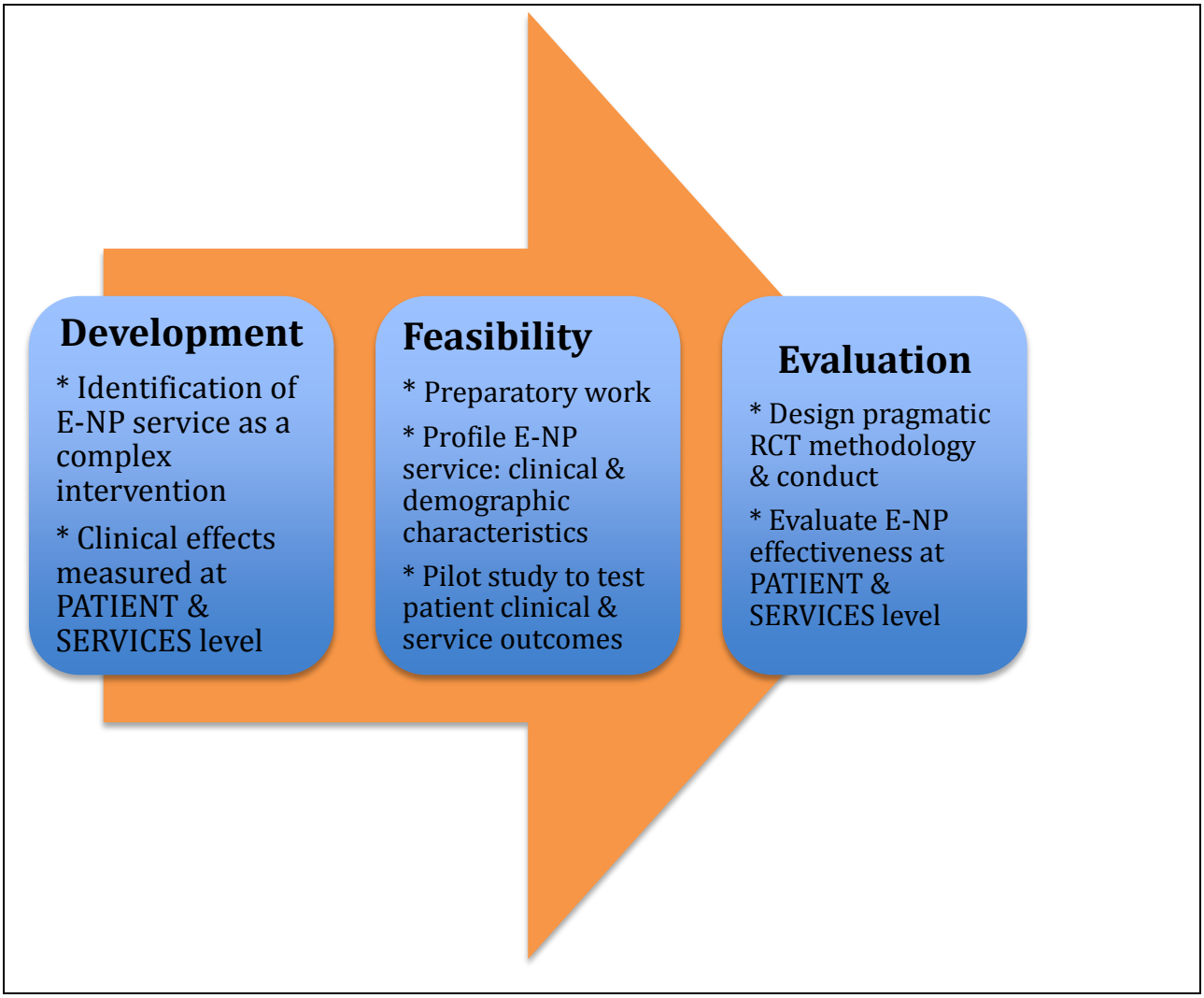
4.3 The methodological approach to evaluate E-NP service

In 2000, The Medical Research Council (MRC) proposed a framework to develop and evaluate complex interventions that recognised the unique challenges that arise in the evaluation process. The MRC framework and its published article have often been cited as authoritative guidance on methods of evaluating such interventions (Medical Research Council, 2000). Specific requirements include a better approach to the development, reporting and implementation of interventions and a greater focus on the contextual features of where the interventions took place (Craig et al., 2013). The MRC has recently updated the original approach with a comprehensive revised guide taking on board the accumulated experiences of researchers that have utilised this approach (Craig et al., 2013). The updated guidelines provided valuable advancements on the original framework, to guide HSR when evaluating complex interventions. The new guideline is intended to help researchers make the appropriate methodological and practical decisions. The model details four key elements to guide the development of a complex intervention though to its evaluation;

- *Development*
- *Feasibility/piloting*
- *Evaluation*
- *Implementation*

Utilising this approach but modifying it to adapt to the already established service of the E-NP, involves a three-tiered process of '*development, feasibility and evaluation' (Figure 2)*.

Figure 2. Key elements' of the E-NP framework



Development: Craig et al., (2013) posit that an early task in developing theoretical understanding of innovations is to identify existing evidence and to identify any theories. The discussion in this chapter has identified E-NP service, as a complex intervention; a hybrid service that includes medicine and nursing. Previously it was established that there are multiple interacting components of the E-NP role and the outcomes of the intervention to be evaluated. The generation of several hypotheses examining effectiveness of patient and service level outcomes has been formulated.

Feasibility/piloting. Craig et al., (2013) report the importance of good pilot work. Study 1 of this research project provided the necessary groundwork to establish information on patient sample characteristics. The findings from Study 1 guided recruitment, data collection methods and

timelines. Study 2 was a pilot study to test the outcome measures retrospectively and refine primary outcomes for the proceeding study. It also allowed for refining of the data collection forms and spreadsheet for data management and engaged the ED setting for the upcoming RCT to commence. The pilot work across these two studies also established the study feasibility. The E-NP service was able to be evaluated subject to the research design accommodating the pragmatic features of an intervention that is already in service.

Evaluation. There are many different study designs available to evaluate complex interventions. Evaluation of E-NP service required a new approach that maintained fidelity to the gold standard of HSR and the design method chosen was an RCT. Craig et al., (2013) suggested randomisation should always be considered as a robust method of reducing bias. Therefore a pragmatic RCT was utilised in this inquiry into E-NP service effectiveness. It was not feasible to ensure double blinding in this study, as the intervention cannot be blinded to the patient groups; identification of the treating practitioner role is an important part of everyday clinical practice. However those involved in data analysis were blinded to the study allocation and the lead investigator was not directly involved ingroup allocation and did not have information about the group code.

The adaptation of the MRC framework (Medical Research Council, 2000) recognises the importance of establishing a theoretical basis for NP interventions (Brazil et al., 2005). This methodological approach builds upon the NP model as a service innovation (Figure 1) within the HSR paradigm to evaluate E-NP service effectiveness. This approach will attempt to understand the relationships between the intervention and the outcomes in two contexts. Namely the:

- Patient care level
- Services level

Patient care level

Time to analgesia and pain score outcomes are direct clinical quality of care indicators that can be measured at the patient level. In the context of high demand for ED services, overcrowding and increased waiting times for assessment, such indicators are a reflection of clinically

important benefits for patients. It is essential to highlight that pain is a very common presenting complaint for emergency patients and its effective recognition and management is an important dimension of the quality of care provided in EDs. Time to analgesia and pain score documentation is one of the mandated clinical indicators implemented by the Australian Council on Healthcare Standards in 2011 (Australian Council on Healthcare Standards, 2011) and hence very appropriate to be measured in examination of E-NP service effectiveness.

Services level

The important clinical indicators of waiting times, length of stay, unplanned representations, and left-without-being-seen rates are essential to ascertain the effectiveness of the intervention at the services level. These indicators are also mandated clinical indicators by the Australian Council of Healthcare Standards (Australian Council on Healthcare Standards, 2011). As ED demand continues to rise it often outstrips enhancements designed to maintain or improve performance. The ability to examine the benefits the E-NP service has implications for other key clinical indicators that can impact not only the ED service but also a whole of hospital service (Lowthian and Cameron, 2012).

4.4 Summary

The NP model is distinctive in health service delivery as an innovation that operates from within a nursing paradigm with the augmentation of medical and other health professionals' skills. This conceptual framework was used to guide this inquiry from a HSR paradigm that evaluated NPs as a service innovation at both the patient and service levels. However, the methodological complexities of evaluating NP service called for a new and dynamic approach to research design considering NP service as an intervention that inherently has a number of interacting elements. To maintain fidelity of the gold standard approach to HSR, a pragmatic RCT was the approach chosen for this research.

Chapter 5. Research methods

5.1 Introduction

Evaluating E-NP service as a complex intervention requires methodology that can accommodate the complexities of the intervention in order to inform decisions about health service planning. As clinicians we attempt to implement evidenced based research not only for health service planning but to optimize safety and quality of care outcomes (The Joanna Briggs Institute, 2014). Methodological quality and rigor of the evidence allows the clinician to base judgment on the results by applying a level of evidence to the research undertaken. Utilizing the Joanna Briggs Institute evidence for practice work (The Joanna Briggs Institute, 2014) hierarchies of the levels of evidence and grades of recommendation have been developed. The levels of evidence for effectiveness outcomes are based on interventions ranked according to study design and other factors. An experimental design is considered level one evidence for effectiveness of an intervention, therefore this research aimed to evaluate the effectiveness of the E-NP model of care using an RCT study design that can conform to high standards of research rigour and also incorporate the naturalist elements of health services research.

5.2 A research design

This research used a pragmatic randomised controlled trial to evaluate E-NP service effectiveness. In consideration of the features and characteristics of the study variables in this project selecting the most appropriate methodology to undertake this health services research required both conventional and innovative methods (Craig et al., 2013). The two experimental designs used in evaluating complex interventions are traditional RCTs and the pragmatic RCT approach (Craig et al., 2013). Table 1 outlines the distinguishing features of each design in order to determine which methodology would align with the conceptual framework, presented in the previous chapter in evaluating a complex intervention.

Table 1. Key elements of RCT designs.

	Traditional RCT	*Pragmatic RCT*
Question addressed	Efficacy- does the intervention work?	Effectiveness- does the intervention work in normal practice?
Setting	Well resourced, controlled environment	Everyday practice
Participants	Homogenous samples, rigorous inclusion/exclusion criteria	Heterogeneous samples, few exclusion criteria
Intervention	Adherence strictly monitored, no deviation to protocol	Flexibility in interpretation of the intervention as it would be in everyday practice
Outcomes	Short term direct relationships	Directly related to needs of the population but often indirect
Internal validity	High- reliability and accuracy of results	Low- Can be maximised by decreasing selection bias through randomisation process, baseline data collection prior to randomisation, blinding data analysis
External validity	Often low- generalisabilty to real world	High- everyday practice applicability

The traditional RCT tests a single, clearly defined intervention focused on efficacy. This approach can be designed with high internal validity with well-defined populations, double blinding and controlled environments, but the design often sacrifices its external validity (Patsopoulos, 2011, Rothwell, 2005). Some factors reported to potentially influence external validity of RCTs include the setting of the study, the selection of the patients', characteristics of the sample and the complexity of the interventions and outcome measures (Rothwell, 2005). Traditional RCT designs control the experimental environment to such an extent that the translation to everyday practice can be limited. Consequently the external validity (or

generalisability) needs to be closely examined when determining the correct methodology to inform evidence in health services research (Hotopf, 2002).

A pragmatic RCT design differs to that of a traditional RCT in regards to the setting, sample, interventions and validity. Pragmatic designs are often characterized as having less control over variables, which comes at a cost of the study's internal validity. The pragmatic design is often reported to have low internal validity due to the limited control in the environment, flexible interventions and heterogeneous samples. Creating a hybrid research design by combining traditional RCT elements (high internal validity) with pragmatic features of everyday applicability (external validity) produces a balance of methodologies to maximise validity of the research. This is a major strength of this design and is relevant to testing health services innovations. Pragmatic RCTs are therefore considered the most appropriate methodology to evaluate complex interventions (Patsopoulos, 2011).

Evaluating E-NP service within a pragmatic RCT design will ensure all the methodological complexities of the intervention are addressed (Table 2). The methodological complexities of E-NP service relate to the number of interacting elements in E-NP service as an intervention (Craig et al., 2013). For example E-NP service is multi-dimensional incorporating clinical, communication and patient teaching skills in a hybrid nursing/medical service model. The connection between this service intervention and the measurable outcomes is often indirect and difficult to evaluate. This pragmatic design will measure a broad spectrum of patient outcomes in order to compare effectiveness of this multidimensional service intervention in everyday practice.

The need to examine the contextual features of E-NP as a complex intervention focuses the research on service effectiveness (Hawe et al., 2004). The E-NP as a complex system intervention enables evaluation to focus on the impact of the model at both the clinical (patient) and health services level.

Table 2. Pragmatic Methodological Complexities and E-NP research

Complexities of E-NP service	*Pragmatic RCT*
Question	Evaluating E-NP service effectiveness in everyday practice
Setting	Emergency Department- high patient turnover, large numbers presenting, dynamic environment
Participants	Minimal exclusion criteria, all ED patients presenting with pain and allocated to Fast track treatment zone
Intervention	E-NP service- complex intervention, hybrid service delivery, multidimensional parts
Outcomes	ED patient outcomes, pain and time to analgesia, use of evidenced based practice, direct and indirect measures
Internal Validity	Baseline data collection prior to randomisation, measures taken to decrease selection bias through randomisation process, blinding data analysis to lead researcher, intention to treat analysis. Additional Measures to reduce bias include separating the different stages of the study ie. Recruitment and baseline data collection, Randomisation (computer generated), outcome data collection and data analysis.
External Validity	Less controlled environment, embedded service that has been operating for 9 years, everyday practice applicability

In order to take into consideration the complexity of evaluating E-NP service a protocol for the RCT was developed. Much of the literature asserts that the publication of a RCT protocol strengthens the standard of the impending research and enables researchers to obtain feedback through the stringent peer review process provided in the publication course (Skogwell and Kramer-Johansen, 2013). Other advantages of publishing a trial protocol includes disseminating information to both patients and researchers as to what trials are currently in practice, provide transparency to the research findings to prevent researchers from revising study outcomes after the trial, and to enhance knowledge production and dissemination of the results (Eysenbach, 2004).

5.3 Publication Four – Protocol.

JAN
Informing Practice and Policy Worldwide through Research and Scholarship

PROTOCOL

A protocol for a pragmatic randomized controlled trial evaluating outcomes of emergency nurse practitioner service

Natasha Jennings, Glenn Gardner & Gerard O'Reilly

Accepted for publication 15 February 2014

Correspondence to N. Jennings:
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Trial registration details: Australian and New Zealand Clinical Trials Registry dated

JENNINGS N., GARDNER G. & O'REILLY G. (2014) A protocol for a pragmatic randomized controlled trial evaluating outcomes of emergency nurse practitioner service. *Journal of Advanced Nursing* 00(0), 000–000. doi: 10.1111/jan.12386

A protocol for a pragmatic randomised controlled trial evaluating outcomes of emergency nurse practitioner service.

Natasha Jennings, Glenn Gardner and Gerard O'Reilly.

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Journal Metrics
Impact per Publication (IPP): 1.65
Google Scholar: 1/20
SCImago Journal Rank (SJR): 1.1 *ISI Journal Citation Reports © Ranking: 2014: 16/104*

5.3.1 Introduction

This protocol describes the main study: a definitive prospective randomized controlled trial, which examined the impact of E-NP service on key patient care and service indicators. The study control arm was standard ED care. The intervention arm was E-NP service. The primary outcome measure was time to analgesia from being seen and from presentation. Secondary outcome measures were waiting time, proportion of patients who did not wait, length of stay in the ED and representations within 48 hours.

Scant research evaluating E-NP service on patient effectiveness and service responsiveness exists currently. This study was an unique trial that evaluated the effectiveness of the E-NP service on patients who present to the ED with pain. The results focus on the impact of the E-NP service model had at both the clinical (patient) and health services level. The research will provide an opportunity to further evaluate E-NP models of care and build research capacity into the workforce. The registration of the trial was completed in September 2013 (Appendix D). The manuscript was accepted in January 2014.

5.3.2 Contribution of authors

This manuscript presents the protocol for the pragmatic randomised controlled trial evaluating outcomes of E-NP service, which is to follow. This protocol was lead by myself under the supervision and guidance of my primary supervisor Professor Glenn Gardner and associate supervisor Dr Gerard O'Reilly. The author team was: N Jennings, G Gardner and G O'Reilly. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship that includes: substantial contribution to the conception of the review; the acquisition, analysis and interpretation of data for the audit; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (Editors, 2014).

5.3.3 Published manuscript

Title

A protocol for a pragmatic randomised controlled trial evaluating outcomes of emergency nurse practitioner service.

Abstract

Aim. To evaluate emergency nurse practitioner service effectiveness on outcomes related to quality of care and service responsiveness.

Background. Increasing service pressures in the emergency setting have resulted in the adoption of service innovation models; the most common and rapidly expanding of these is the emergency nurse practitioner. The delivery of quality patient care in the emergency department is one of the most important service indicators to be measured in health services today. The rapid uptake of emergency nurse practitioner service in Australia has outpaced the capacity to evaluate this model in outcomes related to safety and quality of patient care.

Design. Pragmatic randomised controlled trial at one site with 260 participants.

Methods. This protocol describes a definitive prospective randomised controlled trial, which will examine the impact of emergency nurse practitioner service on key patient care and service indicators. The study control will be standard emergency department care. The intervention will be emergency nurse practitioner service. The primary outcome measure is pain score reduction and time to analgesia. Secondary outcome measures are waiting time, number of patients who did-not-wait, length of stay in the emergency department and representations within 48 hours.

Discussion**.** Scant research inquiry evaluating emergency nurse practitioner service on patient effectiveness and service responsiveness exists currently. This study is a unique trial that will test the effectiveness of the emergency nurse practitioner service on patients who present to the emergency department with pain. The research will provide an opportunity to further evaluate emergency nurse practitioner models of care and build research capacity into the workforce.

Australian and New Zealand Clinical Trial Registry- ACTRN 12613000933752 August 2013.

Key words: nurse practitioner, emergency, protocol, outcomes, clinical trial

SUMMARY STATEMENT

Why is this research or review needed?

- There have been limited rigorous prospective approaches to evaluate effectiveness of nurse practitioner services in the clinical environment
- A hybrid research design approach, by combining traditional randomised controlled trial elements with pragmatic features of everyday applicability will provide a balance of methodologies to undertake this health services research. This pragmatic design will measure a broad spectrum of patient outcomes to compare effectiveness of interventions in everyday practice

Main text of manuscript

INTRODUCTION

Health services research is fundamental to developing knowledge and evidence that can be translated into improvements in access and delivery of healthcare for all patients. Health services research is both multidimensional and multidisciplinary and compliments the myriad of settings in our healthcare landscape. This research paradigm is particularly important when it comes to measuring innovations in service delivery, where innovation is often defined as the introduction of a new model of care, service method or concept, aimed at improving quality of care of patients (Omachonu, 2010).

Delivering health care to meet population needs and increasing demands requires service leaders, policy makers and clinicians to demonstrate leadership to reform existing health services (Council of Australian Governments, 2011). The nursing workforce has responded to these reform imperatives and developed and implemented a range of innovative models of care that promote the concept of healthcare reform. One model of care offering flexibility and adaptation to the changing needs of the consumer population is the nurse practitioner (NP) role. Nurse practitioners were introduced to America and Canada in the 1960's and then further developed into the United Kingdom in the 1980s. Australian NPs were authorised in 2000 as a new model of care for healthcare delivery (Australian College of Nurse Practitioners, 2010).

The nature of NP work involves a hybrid model of care which includes a combination of nursing care, diagnostic activities, intervention-based treatments and the use of medicines; some of these activities have traditionally been limited to the scope of medical practice (Gardner et al., 2010). These innovations to the traditional nursing role have led to recurrent confusion over the role, responsibility, accountability, scope of clinical practice, professional boundaries and effectiveness (Department of Health Queensland, 2012). Furthermore there is scant evidence from well controlled studies that support the effectiveness of nurse practitioner service in terms of the key deliverables of improved patient access, efficiency and quality of patient care to achieve healthcare reform (Rother and Lavizzo-Mourey, 2009, Wilson et al., 2008)

BACKGROUND

One health service area currently under pressure for reform in Australia and internationally are hospital emergency departments (EDs). In Australia EDs have seen more than 7% growth in patient presentations over the last 5 years and this has contributed to an ever-growing burden on the delivery of quality patient care (Lowthian and Cameron, 2012). The capacity of EDs to consistently deliver timely, high quality patient care is impacted by the increase in the number and complexity of presentations.

Emergency department overcrowding, access block, the growing burden of chronic diseases in the community, reduced access to primary healthcare have all contributed to increased demand in ED services (Health Workforce Australia, 2012, Sprivulis et al., 2006, Lowthian et al., 2011). Emergency Department overcrowding is seen as the greatest single impediment to safe and efficient ED services in Australia and New Zealand (Cameron et al., 2009) significantly resulting in increasing waiting times, adverse events, mortality and hospital length of stay (Forero et al., 2010).

National clinical indicators for ED service delivery are now government mandated in several countries and designed to transparently monitor, analyze and evaluate a health service's performance (Department of Health Victoria, 2012, Department of Health United Kingdom, 2011). There are a total of 8 defined clinical indicators compiled by the Australian Council of Healthcare Standards (ACHS) annually to provide clinical perspectives of trends in service and how to improve quality and safety of care for these patients. Emergency department

overcrowding has resulted in the clinical quality indicators of time to analgesia, waiting times, length of stay and mortality becoming adversely affected and impacting effectiveness of patient care (Lowthian and Cameron, 2012). The quality of patient care in the ED requires continuous monitoring and evaluation particularly in the context of high demands for ED services, overcrowding and changing national time performance targets.

A notable clinical indicator in the ED setting commensurate with quality outcomes is time to analgesia and pain score documentation. Acute pain is the most common precursor for patients presenting to Australian EDs (Kelly and Gunn, 2008) and service issues facing the ED today is the ability to deliver timely and effective pain relief. Evaluating the effectiveness of the E-NP service on time to analgesia and pain scores has great implications to provide evidence of quality of patient care. In a joint position statement released by the Australasian College for Emergency Medicine and the College of Emergency Nursing Australasia, pain management is identified as a fundamental component of quality care for ED patients (Australian College of Emergency Medicine, 2012a). Early and effective pain management in the ED setting may also play a pivotal role in reducing the likelihood of chronic pain syndromes and pain-related anxiety and distress following the acute pain encounter (Turturro, 2002, Thomas and Shewakramani, 2008, Weisman et al., 1998). Pain persisting for more than three months (known as persistent pain) can be debilitating and costly to healthcare services (Williamson et al., 2009). Persistent pain significantly impacts patients' physical and mental health and can delay functional recovery following traumatic injury (Castillo et al., 2006, Mkandawire et al., 2002). The development of interventions for the prevention of persistent pain correlates with earlier and more effective

treatment of acute pain to reduce or even terminate the progression from acute to persistent pain and improve patient quality of care (Mkandawire et al., 2002, Castillo et al., 2006).

Differences in pain scores and treatment effectiveness will be evaluated throughout the study. In 2007, the Australian National Institute of Clinical studies (NICS) sanctioned 'The NICS National Emergency Care Pain Management Institute' for the implementation of best practice in relation to ED pain management. As a result, a national audit of 36 hospitals throughout Australia (n=1996) was conducted and results showed that a median time to analgesia in the ED was 61minutes, where 30 minutes was considered the national standard by ED care experts (Herd et al., 2009). The study also discovered that less than 40% of patients sampled had a pain score documented at triage. The clinical indicators recommended from the report were a target of 80% of patients presenting to the ED have a documented pain score within 30 minutes, a median time to analgesia of 30 minutes from triage and their Visual Numeric Pain Score (VNPS) reduced by a score of 3 points within 60 minutes of arrival to ED.

The major recommendation from the Australian Health Workforce Advisory Committee's evaluation of ED models of care was the need to address service issues in the ED with innovative models and workforce reform. The developments of innovative models of care have been strategies to address some of these issues. The E-NP role is part of a reformative model of health service that has the potential to directly impact service outcomes and quality of patient care.

THE STUDY

Aims

The aims of this research are to compare the effectiveness of E-NP on service and quality of patient care outcomes, with that of standard care in the ED. Hence the following null hypotheses will be tested:

> For patients presenting to the ED with pain, allocated to the fast track zone and who receive care from either an E-NP or standard care, there will be no difference in:

Primary outcomes

1. Pain score reduction and time to analgesia

Secondary outcomes

2. Service indicators of
    1. Waiting time
    2. Number of patients who did-not-wait
    3. Length of stay in emergency department
    4. Representations with 48 hours

In addition, a comparative evaluation of clinicians' use of evidence based guidelines for management of: i) knee injury; ii) ankle injury; and iii) burns injury will be conducted to further test the integrity of the intervention.

METHODOLOGY

The nurse practitioner model is distinctive in health service delivery as an innovation that operates from within a nursing paradigm augmented by medical and other health professional's skills. The methodological complexities of evaluating NP service relate to the nature of NP service as an intervention that is inherently multidimensional with several interacting elements. Examining this service as a complex intervention will focus the research on patient and service effectiveness and provide an appropriate framework to guide this study.

A pragmatic RCT design differs from a traditional RCT in regards to the setting, sample, interventions and the nature and level of research validity. Pragmatic designs are often characterized as having less control over variables, which come at a cost of its internal validity. The design is often reported to have low internal validity due to the limited control in the environment, flexible interventions and the heterogeneous nature of the study sample. Creating a hybrid research design by combining traditional RCT elements (high internal validity) with pragmatic features of everyday applicability (external validity) produces a balance of methodologies to maximise validity of the research. This is a major strength of this design and is relevant to testing health services innovations such as E-NP service.

The methodological complexities of E-NP service relate to the number of interacting elements in E-NP service as an intervention (Craig et al., 2013). For example E-NP nursing service is multi-dimensional incorporating clinical, communication and patient teaching skills in a hybrid nursing/medical service model. The connection between this service intervention and the

measurable outcomes is often indirect and difficult to evaluate. This pragmatic design will measure a broad spectrum of patient centered outcomes to compare effectiveness of interventions in everyday practice of the most common outcomes in the ED setting (Hotopf, 2002). Ethical approval was gained in December 2013 for commencement scheduled for February 2014.

Study site

This is an Australian study that will be conducted in an urban, Emergency and Trauma Centre (hereafter referred to as the ED), in Melbourne, Victoria. The ED, is a tertiary public hospital affiliated with several Universities. The hospital has provided emergency services since opening in 1871 and a statewide trauma services since 1989. The current integrated ED facility was commissioned in 1999. In addition to providing emergency services to the local community, the ED also provides Victorian statewide services for: Trauma (adult) and Burns (adult), Hyperbaric Medicine, HIV Medicine, Cystic Fibrosis (adult) and Haemophilia (adult), Heart & Lung Transplant, Critical Neurosurgery.

The ED is a purpose built modern facility consisting of eight Resuscitation and Trauma Bays, nineteen fully monitored general cubicles (including six rapid assessment cubicles) along with six Fast track zone cubicles. In addition there is also a co-located eighteen bed Short Stay Unit. The Trauma service treats more than 1200 major traumas annually which represents greater than half of all major traumas in the state of Victoria, with an estimated annual ED attendance of 65,000 in the year 2012 (Department of Health Victoria, 2012). Approximately 30% of these patients are managed in the Fast track zone.

The Fast track zone in the ED is a geographical area adjacent to the main ED connected by a corridor. This area is an adjunct to processes in a treatment pathway designated for the timely assessment, treatment and discharge of people seeking primary care for less serious illnesses and injuries. The six individual cubicles are centered around a staff base station and operate on a 24-hour basis. A multidisciplinary team that may include registered nurses, medical officers, registrars, ED consultants, musculoskeletal physiotherapists and E-NPs, provides the services in Fast track. Emergency nurse practitioners work in the Fast track zone from 0700hrs to 23330hrs on a combination of eight and ten hour shifts. All patients presenting to the ED are triaged on arrival and an Australasian Triage Scale (ATS) category allocated (Australian College of Emergency Medicine, 2012a). The ATS is designed for use in hospital-based emergency services throughout Australia and New Zealand. The ATS is a scale for rating clinical urgency and used to ensure that patients are seen in a time frame that is commensurate with the clinical urgency of their presenting symptoms.

Inclusion/exclusion criteria

The study population is all patients presenting to the ED during the sampling time frame and allocated for their episode of care to the Fast Track zone. All eligible patients will be approached by the clinical research assistants using a standardised recruitment script. The eligibility criteria for enrolment in this research are included (Table 1).

Table 1. Emergency nurse practitioner (E-NP) trial eligibility criteria

E-NP study- Inclusion Criteria
○ Age >16 years ○ Patient presentations ATS 2-5 ○ Pain identified in triage description

E-NP study Exclusion Criteria
○ Non English speaking ○ Neurovascular compromise ○ Multiple injuries ○ Altered conscious state including effects of drugs/ Ethanol ○ Glasgow Coma Scale <14 ○ Fulfils inclusion criteria but requires immediate medical management

Randomisation

Consenting patents in series will be randomly assigned to either the intervention or the control group by a computer-generated process. The clinical research assistants (CRA) will telephone the offsite randomisation service that will allocate study participants using block randomisation. Randomisation gives each patient a chance of being assigned to either the intervention or control groups. Successful randomisation practices require that group assignment cannot be predicted in advance. Block randomisation is used to ensure appropriate distribution across the two treatment arms and help to reduce bias and confounding, especially when the sample size is small (Efird, 2011). Allocation will adhere strictly to the generated sequence with block sizes of four. For

every block of four patients, for example, two would be allocated to each arm of the trial (A = intervention and B = control), with block configurations randomly assigned. To strengthen methodological rigour, CRA's and the randomisation process will all be independent of other components of the study design. A flow diagram outlining the trial design is shown in Figure 1.

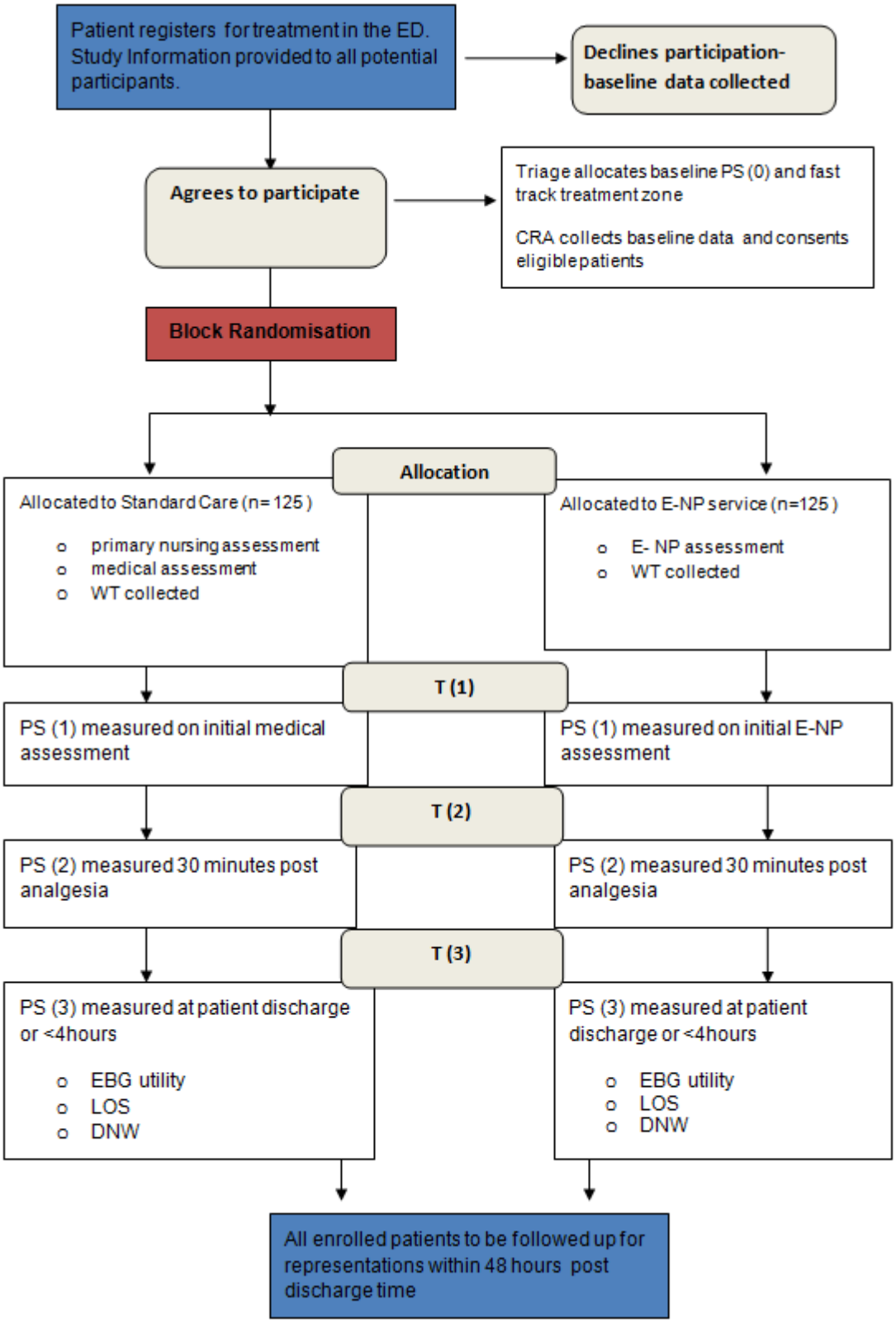
Patient registers for treatment in the ED. Study Information provided to all potential participants.
Declines participation- baseline data collected
Agrees to participate
Triage allocates baseline PS (0) and fast track treatment zone
CRA collects baseline data and consents eligible patients
Block Randomisation
Allocation
Allocated to Standard Care (n= 125)
primary nursing assessment
medical assessment
WT collected
Allocated to E-NP service (n=125)
E- NP assessment
WT collected
T (1)
PS (1) measured on initial medical assessment
PS (1) measured on initial E-NP assessment
T (2)
PS (2) measured 30 minutes post analgesia
PS (2) measured 30 minutes post analgesia
T (3)
PS (3) measured at patient discharge or <4hours
EBG utility
LOS
DNW
PS (3) measured at patient discharge or <4hours
EBG utility
LOS
DNW
All enrolled patients to be followed up for representations within 48 hours post discharge time

Figure 1.

Study intervention

The intervention to be evaluated in this research will be E-NP service. The emergency nurse practitioner model of care specifically includes assessment and management of patients using critical decision-making skills, referring directly to other health care providers, prescribing medications, performing interventions, ordering and interpreting diagnostic investigations and admission/discharging autonomy. The E-NP will assess the next available patient in their scope of practice according to time waiting to be seen as per usual ED policy. After this initial assessment the E-NP will commence management of the patient and complete the episode of care. The service is geographically located in the Fast track area of the ED and the E-NP manages patients presenting with ATS categories 2-5 (Australian College of Emergency Medicine, 2012a). The E-NP works closely with the registered nurse allocated to the Fast track zone, sharing care responsibilities such as collecting and recording assessment data, administering medications and flow through the area.

Study control

The study control will be standard ED care, which is operationally defined as medical officer managed care with assistance from registered nurses. Medical officers covering the fast track zone are emergency medicine registrars with a minimum of 3 years post basic training and are currently undertaking advanced training to be registered as a fellow of the Australian College of Emergency Medicine. Consistent with effectiveness studies in health service research, standard ED care will be practiced in accordance with usual ED policy with no changes to the model. The patient is allocated to the Fast track zone and the next available clinician will commence the initial assessment. The registered nurse or the medical officer may undertake this initial

assessment but management decisions will be made by the medical officer and then completed by the standard ED care team members in the Fast track zone.

Sample size

The primary study outcome will be comparison of the intervention and control groups in relation to time to analgesia and pain scores. This will be measured as yes or no against the national standard of best practice in time to analgesia in the ED (Council, 2011), which is patient treatment within 30 minutes of arrival. A 20% change of compliance with the 30 minute standard between the two groups was considered to be clinically important. Sample size calculations will be based on 80% power and a type 1 error rate (two sided) of 0.05 and adjusted for an estimated loss to follow-up of 20%. Consequently the sample size was calculated to total 260 patients; 130 patients per arm of the study.

Data collection

Baseline data will be collected from all consenting patients. These patients will then be followed through to ED disposition. Eligible patients, consented and then enrolled in the study will then be followed through to ED disposition. A detailed data spread sheet was designed and subsequent data will be collected from the ED patient information system/electronic heath record and the patient. These data will be collected by the Outcomes Research Assistants (ORA) on the data collection form and then uploaded to a data file. The following is a list of data fields to be collected by the research assistants.

PS (0) – initial pain score performed at triage.

The triage nurse will conduct the initial pain assessment and record the score (VNPS) on all patients presenting to the ED registering for treatment on the patient's electronic record. This is usual ED practice for the triage nurse and assists the nurses in clinical decision making to award ATS prioritisation for patients. This will then be recorded by the CRA with baseline data on the E-NP RCT data collection form.

Baseline demographics

The CRA will collect baseline data from eligible, consenting patients on recruitment. Generic demographic details will be collected to include, date, time, age, sex, ATS category assigned, mode of transport to the ED, whether the patient had administered analgesia prior to arrival to the ED, its type and the dose of analgesia taken.

The ORA will review the ED patient information system/patient's electronic health record and collect and record outcome data:

- *PS (1) – subsequent pain score by treating clinician on initial assessment.*
- *PS(2) – pain score at 30 minutes post administered analgesia*
- *PS(3) – pain score at discharge from ED <4hours from arrival time*
- *EBG – use of evidenced based guidelines*
- *LOS – time measured from initial registration until ED disposition*
- *DNW- determine if patient waited for treatment*

- *Representation – determine if patient returned to the ED for unexpected visit for same presenting complaint within 48 hours of disposition*

Data analysis

The 30-minute 'Target Achieved' variable will be considered as binary (yes/no for achieving the target time of 30 minutes). The difference in 'time to analgesia' tested by t-test or Wilcoxon Rank Sum depending on the distribution. Using 30 minutes as best practice for time to analgesia for patients presenting with pain to the ED, we felt a difference of 20% between the two groups to be clinically important. Data analysis will be conducted on an intention to treat bias. Standardised and validated data collection instruments will be used. Demographic data will be collected as with other confounders. Physical data such as pain score assessment will be recorded on the patients' electronic health record and audited by the CRA and ORA. Descriptive statistics will be used to summarise the data. For normally distributed continuous data, results will be expressed as mean (standard deviation); comparisons between the two groups will be examined using the independent t-test. For continuous data that is not normally distributed, results will be expressed as median (interquartile range); comparisons between the two groups will be examined using the Wilcoxon rank sum test. Binary data will be displayed as a proportion (percentage); comparisons between the two groups will be examined using the Chi^2 test. A statistician will be used to inform and guide the interpretation of the differences between groups in relation to study outcomes. The CONSORT 2010 statement will be used to guide the reporting of this RCT (Schulz et al., 2011). It is envisaged that these tools will foster complete, clear and transparent reporting of the results of this research.

Ethical considerations

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia (Council, 2007). Ethical clearance by the University and the Hospitals Human Research Ethics Committees was approved in December, 2013. All participants will be given study information and consent documents and invited to participate in the study. The information document will describe the purpose of the study, the procedures to be followed and the risks and benefits of participation. Prior to enrolling in the study a signed consent form will be obtained for each patient. Participants will also be assured that all data will be stored in a secure place and confirmation of continuing consent will be sought verbally from participants during their treatment.

Rigour

The research will be a pragmatic RCT design to evaluate our intervention to reduce inherent methodological issues when conducting health services research (Donner and Klar, 2001). Creating a hybrid research design by combining traditional RCT elements (high internal validity) with pragmatic features of everyday applicability (external validity) produces a balance of methodologies to maximise validity of the research. This is a major strength of this research design and is relevant to testing health services innovations. Evaluating E-NP service in a pragmatic RCT design will ensure all the methodological complexities of the intervention are addressed (Table 2).

Table 2- Methodological complexities of Emergency Nurse Practitioner (E-NP) services

Complexities of E-NP service	*Pragmatic Randomised Controlled Trial*
Question	Evaluating E-NP service effectiveness in everyday practice
Setting	Emergency Department- high patient turnover, large numbers presenting, dynamic environment
Participants	Minimal exclusion criteria: all ED patients presenting with pain and allocated to Fast Track treatment zone
Intervention	E-NP service- complex intervention, hybrid service delivery, multidimensional parts
Outcomes	ED patient outcomes, pain and time to analgesia, use of evidenced based practice, direct and indirect measures
Internal Validity	Baseline data collection prior to randomisation, measures taken to decrease selection bias through randomisation, blinding treatment allocation to lead researcher, intention to treat analysis. Additional Measures to reduce bias include separating the different stages of the study i.e. Recruitment and baseline data collection, Randomisation (computer generated), outcome data collection and data analysis.
External Validity	Less controlled environment, embedded service that has been operating for 9 years, everyday practice applicability, effectiveness study

DISCUSSION

Over the last decade, NP models of care have been implemented in ED's as a strategy to improve access, efficiency and quality of care outcomes for patients (Wilson et al., 2008). There is a significant gap in the research evaluating the effectiveness of E-NP service on quality of patient care and service responsiveness in Australia and abroad. It is difficult to make comparison with the existing evidence due to operational differences such as standardised definitions of NPs,

funding models of ED workforce and the quality of the research conducted. This paucity of research lends itself to the development of a robust pragmatic trial of effectiveness of E-NP service delivery.

Despite the rapid uptake of E-NP service in EDs there has been limited rigorous prospective approaches to evaluate effectiveness. However choosing the most appropriate methodology to undertake health services research requires both conventional and innovative methods (Craig et al., 2013). This trial will be, to our knowledge, the first E-NP intervention research to evaluate outcomes relating to time to analgesia and pain scores used to evaluate quality of care outcomes. This trial will address key clinical targets for the ED care of patients with pain, which has significance for both Australia and international EDs. This protocol will also serve as an example of developing a protocol for a pragmatic randomized controlled trial for health services research.

Limitations

This study will focus on a small sample of patients in one urban ED where service is managed by NPs and standard ED care. Therefore generalizability of the results needs to be considered. It is anticipated that this study will provide some empirical data to build on the evidentiary basis to evaluate NP service effectiveness in regards to significant patient clinical indicators.

Author contributions

All authors have made substantial contributions to design of the study, drafting the manuscript and critically revising it for its intellectual content. All authors have read and approved the final manuscript and take responsibility for its content.

Trial registration details: Australian and New Zealand Clinical Trials Registry dated 18th August 2013, ACTRN 12613000933752.

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5.4 Data management

The remainder of the chapter will present the processes used in data management training for research assistants, data cleaning, project promotion and analysis. These components are all integral to the pragmatic RCT design.

Research assistant education and credentialing

Recruitment of research staff was achieved through engaging medical students and department nursing staff. Medical students, located in the study setting, were selected via an expression of interest to participate in research activities. The expression of interest flyer outlined the research objectives (Appendix D). Expressions of interest flyers were also placed in the staff tearoom and conveyed during nursing communication meetings at the beginning of each ED shift. Throughout January, the lead researcher attended and informed staff of the upcoming trial and reiterated the opportunity for staff to participate as research assistants. A total of four medical students and four registered nurses were in the initial cohort of staff who volunteered as research assistants (RA). A performa of the RA duties was also developed and formed part of the training module (Appendix E). The research assistants were allocated to either Clinical Research Assistants (CRA) or Outcome Research Assistant (ORA) roles. The CRAs undertook the recruitment and baseline data work and the ORAs completed data collection and entry. This separation of functions between the CRAs and ORA roles assisted to reduce any bias during the phases of the data collection. In the naturalistic setting of the ED, it is important to try and minimise bias and reduce any threats to the validity of the results.

Education and training of RAs included a PowerPoint presentation outlining the methodology, recruitment of patients, informed consent and data collection procedures. The RCT protocol was published and available and used as a tool to assist with training. Once completed, all CRAs were buddied with the lead researcher for their first shift of recruitment to oversee accuracy of recruitment, baseline data collection and the randomisation procedure. The initial cohort of medical students completed their ED rotation over a 8-week period from 01 January 2014 to 31

February 2014, which required a further re expression of interest, recruitment and training of RAs to continue patient enrolment. A total of six new staff participated in the second round of training and data collection supervised by the lead researcher.

Data collection tools

Data collection forms were designed to ensure consistent and time efficient data entry (Petrie, 2009) (Appendix H). Baseline and outcome hardcopy forms were used to reduce time required interviewing patients and delaying allocation of the trial interventions. All data collection forms were located in a dedicated office adjacent to the study area. The data collection forms were designed to include a separate box for categorical data and for codes assigned to either single or multi coded variables. Numerical data were also entered using a 24 hour clock in the 00:00 format. Once baseline data input was completed the randomisation card was stapled to the form and placed into a locked filing cabinet. The forms were collected at the end of each shift by the lead researcher and stored in compliance with the ethics requirements. The patient information and consent form template is reproduced in Appendix H.

A Microsoft Excel™ spreadsheet design was developed after creating a list of all variables to be collected and published in the protocol. The spreadsheet was also tested during the pilot study to ensure accuracy and ease of use.

Different RA groups within the study site undertook each stage of the data collection and entry. Separating the different stages of the study i.e. recruitment and baseline data collection, randomisation (computer generated), outcome data collection, data entry and data analysis, was used as an additional measure to reduce bias. A recruitment flowchart outlining data collection was developed and presented during the RA training program. The flowchart was also placed strategically next to recruitment packs for easy reference for all RAs in the research office.

Baseline data collection was undertaken by the RAs in the treatment area. Follow up outcome data were collected by the ORA. The RAs were located in an office away from the clinical environment to reduce interruptions and minimise noise disturbance. The medical student utilised for the pilot study as the ORA, was used again for the data entry of all baseline and outcomes data into the spreadsheet.

5.5 Summary

The protocol publication for this research established awareness to the emergency services community, E-NPs and health services researchers of the forthcoming pragmatic RCT. This attempted to alert the scientific community and assist in subsequent translation of evidence into practice. Emergency nurse practitioner research has needed to move beyond retrospective, qualitative research to produce high quality evidence of efficiency, productivity and clinical outcomes to develop and sustain the role into the future.

Despite the rapid uptake of E-NP service in EDs, there have been limited rigorous prospective approaches to evaluate effectiveness. However, choosing the most appropriate methodology to undertake health services research requires both conventional and innovative methods (Craig et al. 2013). This trial is the first E-NP interventional research to evaluate outcomes relating to time to analgesia and pain scores as an indicator of quality-of-care outcomes. The protocol will also serve as an example of developing a protocol for a pragmatic randomized controlled trial for health services research and particularly NP services.

Chapter 6. Results

6.1 Introduction

The aim of this research was to evaluate E-NP clinical and service effectiveness, in order to advance knowledge and contribute an evidence base for policy and health service planning. This chapter will present the findings from this study; findings that demonstrate the effectiveness of E-NP service in terms of both clinical patient care and service outcomes in the ED setting. The methodological processes that combined a robust review of research evidence, sound preparatory work, appropriate methods and data tools and a guiding conceptual framework, have resulted in findings that meet the aims of this research.

6.2 Patient care and service level results.

Effectiveness of E-NP service was evaluated at both the patient care level and service level (Figure 1- page 123). This approach was necessary as HSR aims to provide robust evidence that can influence health service policy to impact health outcomes (Black, 1997). Previously we have acknowledged a lack of evidence surrounding the measurement of direct clinical patient outcomes with E-NP service. The ability to research both elements of this service innovation is unique and moves the body of this new contemporary evidence to a level that has not been seen before. The hybrid nature of the NP role, with its multiple components requires this unique level of evaluation. These factors all aim at improving patient outcomes delivered at the patient and/or the health service level.

6.3 Publication Five– Patient care level results

The effectiveness of emergency nurse practitioner service on timely management of analgesia clinical patient care outcomes – A pragmatic randomised controlled trial

Natasha Jennings, Glenn Gardner, Gerard O'Reilly and Biswadev Mitra.

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6.3.1 Introduction

Acute pain is the most common presenting complaint for patients attending Australian EDs (Doherty et al., 2013, Finn et al., 2012, Holdgate et al., 2010, Kelly and Gunn, 2008) and management of acute pain is one of the national clinical indicators to assess service performance and quality of care. Timely analgesia is an important clinical indicator of ED service performance and quality of care. Timely analgesia and the documentation of pain scores are the key clinical quality indicators compiled by the Australian Council of Healthcare Standards (Australian Council on Healthcare Standards, 2011). No previous studies evaluate time to analgesia effectiveness provided by E-NP services in comparison with standard ED care.

6.3.2 Contribution of authors

This manuscript presents the effectiveness of emergency nurse practitioner service on clinical patient care outcomes – A pragmatic randomised controlled trial, which is to follow. The ethics for the trial is included in Appendix G. This RCT was lead by myself under the supervision and guidance of my primary supervisor Professor Glenn Gardner and associate supervisor Dr Gerard O'Reilly. The author team was: N Jennings, G Gardner, G O'Reilly, B Mitra. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship that includes: substantial contribution to the conception of the review; the acquisition, analysis and interpretation of data for the audit; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (Editors, 2014).

6.3.3 Manuscript copy

Title

The effectiveness of emergency nurse practitioner service on timely management of analgesia clinical patient care outcomes – A pragmatic randomised controlled trial

Authors

Natasha Jennings, Glenn Gardner, Gerard O'Reilly, Biswadev Mitra.

Abstract

Background

The rapid uptake of Nurse Practitioner (NP) service in Australia has outpaced evaluation of this service model. A randomised controlled trial was conducted to compare the effectiveness of nurse practitioner service versus standard medical care in the ED of a major referral hospital in Australia.

Methods

Patients presenting with pain were randomly assigned to receive either standard ED medical care or NP care. Primary investigators were blinded to treatment allocation for data analyses. The primary outcome measure was the proportion of patients receiving analgesia within 30 minutes from being seen by care group. Secondary outcome measures were time to analgesia from presentation, documentation and changes in pain scores

Results

There were 260 patients randomised, with 128 receiving standard ED medical led care and 130 receiving NP care. The proportion of patients who received analgesia within 30 minutes from being seen was 49.2 %(n=64) in the NP group and 29.7% (n=38) in the standard group, a difference of 19.5% (95% CI: 7.9-31.2%, p=0.001). Of 165 patients who received analgesia, 64 patients (84.2%) received analgesia within 30 minutes in the NP group compared to 38 patients (42.7%) in the standard care group, a difference in proportion of 41.5% (95% CI: 28.3-54.7%, p <0.001. Mean time from being seen to analgesia was 25.4 (SD 39.2) minutes for NP care and 43.0 (SD 35.5) minutes for standard care, a difference of 17.6 minutes (95% CI: 6.1-29.1, p=0.003). There was a difference in the median change in pain score of 0.5 between care groups but this was not statistically significant (p=0.13).

Conclusion

Nurse practitioner service effectiveness was demonstrated through superior performance in delivery of timely analgesia for ED patients.

Trial registration details

Australian and New Zealand Clinical Trials Registry dated 18th August 2013, ACTRN 12613000933752.

Key words

Nurse practitioners, emergency service, quality of health care, pain, analgesia, RCT

Main text of manuscript

Background

Emergency departments (ED) have seen more than 7% growth in patient presentations over the last 5 years and this has contributed to an ever-growing burden on the delivery of quality patient care 1. The capacity of EDs to consistently deliver safe, timely and quality patient care is impacted by the increase in the number and complexity of presentations. The increasing incidences of chronic disease in the community, reduced access to primary healthcare and fewer general practitioners have contributed to this increased demand in ED services [2,3,4.]

A range of innovative service and workforce models have been developed to address these issues [2.] One of these is the nurse practitioner model of care. Nurse practitioners are nurses with advanced educational preparation and experience, with authorisation to practice in an expanded hybrid model, holding both nursing and medical skills with an emphasis on health promotion, education and holistic care [5]. The nurse practitioner model of care was first introduced to the USA and Canada in the 1960s as a substitute for primary care physicians[6] in under-serviced areas. The movement then developed in the UK and later Australia in 2000. Nurse practitioners who work in Australian EDs hold emergency specialist qualifications. [7,8.]

Evaluation of the effectiveness of nurse practitioner service on patient clinical outcomes is essential for establishing the value of this model to health service improvement. There is a growing body of research indicating that nurse practitioner service in the ED positively impacts favourably on patient satisfaction and waiting times [9,10,11]. However there has been limited robust evaluation of nurse practitioner service effectiveness on clinical outcomes and patient quality of care[12]. A recent systematic review[13] confirmed only one study, using a small convenience sample, attempted to evaluate emergency nurse practitioner service impact on patient quality of care with patient reported outcomes.

Acute pain is the most common presenting complaint for patients attending Australian EDs[14,15,16,17,] and management of acute pain is one of the national clinical indicators to assess service performance and quality of care. Timely analgesia and the documentation of pain scores are the key clinical quality indicators compiled by the Australian Council of Healthcare Standards[18]. A median time to analgesia following presentation to the ED of 30 minutes is the

national standard, but in practice, has been shown to be longer [19,20,21,14,22]. Poor documentation of pain scores has also been consistently demonstrated[24,23,24,25,14]. Ineffective and/or delayed analgesia for patients attending the ED is another common feature in the literature[23,26] and represents an area requiring further investigation.

Importance

A joint policy released by the Australasian College for Emergency Medicine and the College of Emergency Nursing Australia[27] identified acute pain management as a fundamental component of quality of care for ED patients. Early and effective pain management in the ED setting may also play a pivotal role in reducing the likelihood of chronic pain syndromes, pain-related anxiety and distress following an acute pain presentation [28,29,32]. Previous studies have highlighted the response by health professionals to the management of acute pain in the ED as sub optimal and clinically ineffective [28,30.] It is therefore important to evaluate the timely and effective delivery of analgesia for ED patients. The effectiveness of nurse practitioner service on the delivery of timely analgesia as a patient clinical outcome has previously only been evaluated by a small retrospective chart review [22]. In that study the median time to analgesia from being seen was [25] (IQR 12-50) minutes with 61.3% (95% CI: 51.4 – 70.6) of patients receiving analgesia within 30 minutes of assessment[22]. No previous studies were found evaluating time to analgesia provided by nurse practitioner services in comparison with standard ED care.

The aim of this study was to evaluate nurse practitioner effectiveness in delivering analgesia within the Australian national target of 30 minutes from being seen by the treating care group.

METHODS

Study design and setting

This was a pragmatic randomised controlled trial to evaluate the impact of NP service on time to analgesia. The trial was undertaken in one adult tertiary level four ED with an annual census in 2013 of over 65,000 patients[31]. The nurse practitioners in this setting are located in the fast track zone, which is designated for timely assessment, treatment and discharge of patients seeking primary care type services and comprises approximately 30% of patient presentations[32,10]. The 'fast track' is staffed by nurse practitioners between the hours of 0700 and 2330, and medical

officers between the hours of 1000 and 2030. Both staffing models see and treat the same cohort of patients in the fast track zone in order of triage category. The nurse practitioner service model includes assessment and management of patients in Australasian Triage Scale (ATS) categories [33], both independently and collaboratively within this established ED model of care. The triage nurse assesses all patients on arrival to the ED and directs patients assessed as suitable for fast track care to the zone according to protocol and presenting complaints. The aims, methods and protocol of this study have been previously reported[34].

This study was conducted according to the National Statement on Ethical Conduct in Human Research, 2007 [35]. Approval was obtained from the relevant University and hospital Human Research and Ethics Committees.

Selection of participants

All patients presenting to the ED with a complaint of 'pain' and allocated for their episode of care to the 'fast track' zone were eligible for inclusion in the trial. 'Pain' needed to be identified in their triage description and recorded in the ED patient information system (Cerner Firstnet™) as part of the inclusion criteria. Patients were excluded if their Verbal Numeric Pain Scale (VNPS) was <1 at the point of potential enrolment. Patients who were non-English speaking, had multiple injuries or altered conscious states were excluded from participation in the study. Patients were required to provide written informed consent to participate in the study. The clinical research assistants used an examination cubicle to recruit and consent patients and collect baseline demographic information. The first patient was enrolled in February 2014.

Randomisation

Following collection of baseline data, consenting patients in series were randomly assigned to receive either standard care (control) or nurse practitioner care (intervention). Randomisation was performed with an allocation sequence of four and generated by computer random number generator and then transcribed into opaque sequentially numbered sealed envelopes. Each envelope contained a card with the allocation group recorded and treatment pack. Allocation adhered strictly to the generated sequence and was maintained. Both participants and treating staff were aware of treatment allocation. All treating staff were given the same trial information

before commencement. Information included that the trial purpose was investigating nurse practitioner effectiveness. No treating staffs were aware of any of the trial outcomes. The primary investigator was blinded to the allocation groups for analysis of the results. Analysis was undertaken on an intention to treat basis.

Interventions

Patients allocated to the control group were managed by a medical officer with assistance from registered nurses, if required. The medical officers consisted of 17 emergency medicine registrars with a minimum of 3 years post-graduate training and were undertaking advanced training towards fellowship of the Australasian College for Emergency Medicine. The fast track zone allocation was a component of the medical officers' training program. Medical officers were exclusively dedicated to the 'fast track' zone. All medical officers rotated through the zone during the trial. Standard ED care was practiced in accordance with usual ED policy with no changes to the model during the study period. The patient was allocated to the 'fast track' zone and the next available clinician commenced the initial assessment.

The intervention group was managed by nurse practitioners. The emergency nurse practitioner provides autonomous, comprehensive care assisted, when necessary by a registered nurse. After initial assessment, the nurse practitioners commence management of the patient and complete the episode of care. There were nine nurse practitioners rostered to the fast track zone, all of whom were accredited and endorsed and holding specialist emergency care qualifications. In Australia, nurse practitioners can only prescribe analgesics after accreditation. Our nurse practitioner cohort has been accredited from 1 to 4 years.

Outcome measures

The primary outcome measure was the proportion of patients who received analgesia from time seen by care group within the Australian national target of 30 minutes. Secondary outcome measures were time to analgesia from ED arrival, changes in pain scores and documentation of pain scores. Time to analgesia from being seen was recorded as the time taken to have analgesia administered from initial patient assessment by the care provider. Time to analgesia from ED arrival is defined as the time taken from patient registration until the administration of analgesia.

Data collection

In order to strengthen methodological rigour, different research assistants undertook each stage of the trial and data entry. Separating the different phases of the study i.e. recruitment and baseline data collection, randomisation (computer generated), outcome data collection, data entry and data analysis (lead researcher), was used as an additional measure to reduce bias. Two data collection forms were developed to collect baseline characteristics and outcome data. The clinical research assistants obtained baseline data directly from the patient. The outcome research assistants collected data from the ED patient information system/electronic heath record that were recorded prospectively during the patients' episode of care. The triage nurse performed the initial pain assessment and recorded the VNPS on all patients, in accordance with usual ED practice.

All data were entered into a Microsoft Excel™ spreadsheet for blinded analysis. To ensure the highest accuracy and quality of data, strategies were used to minimise errors during data processing. A list of all values contained within the variables in the dataset were listed and then crosschecked to determine if there were any responses that were outside these values. Any outliers were verified against the original data forms. Verification entry was undertaken to determine if there were any coding errors related to the miscoding of patients' responses and 10% of all data forms were randomly selected by the lead researcher to compare the entered data with the hard data collection forms[36].

Statistical analyses

Sample size calculations were based on 80% power and a type 1 error rate (two sided) of 0.05 and adjusted for an estimated loss to follow-up of 20%. The investigators considered a minimum 20% difference in compliance between the two groups with the primary outcome measure was considered to be clinically significant. The sample size was calculated to enrol 260 patients; 130 patients per arm of the study.

Normally distributed continuous variables were presented using the mean (standard deviation), and ordinal or skewed data presented using the median (inter-quartile range). To determine statistical significance, Student's t-test was used to compare two means, Wilcoxon Rank Sum was used to compare two medians, and the chi-squared (□2) test was used to compare two

proportions. Further analysis of time from being seen to analgesia was conducted using a Kaplan-Meier graph. A p-value of less than 0.05 was considered statistically significant. All analyses were performed using Stata version 12.0 (Statacorp, College Station, TX, USA).

RESULTS

Characteristics of study subjects

Table 1 provides a summary of all patient characteristics.

Table 1. Baseline data of eligible participants

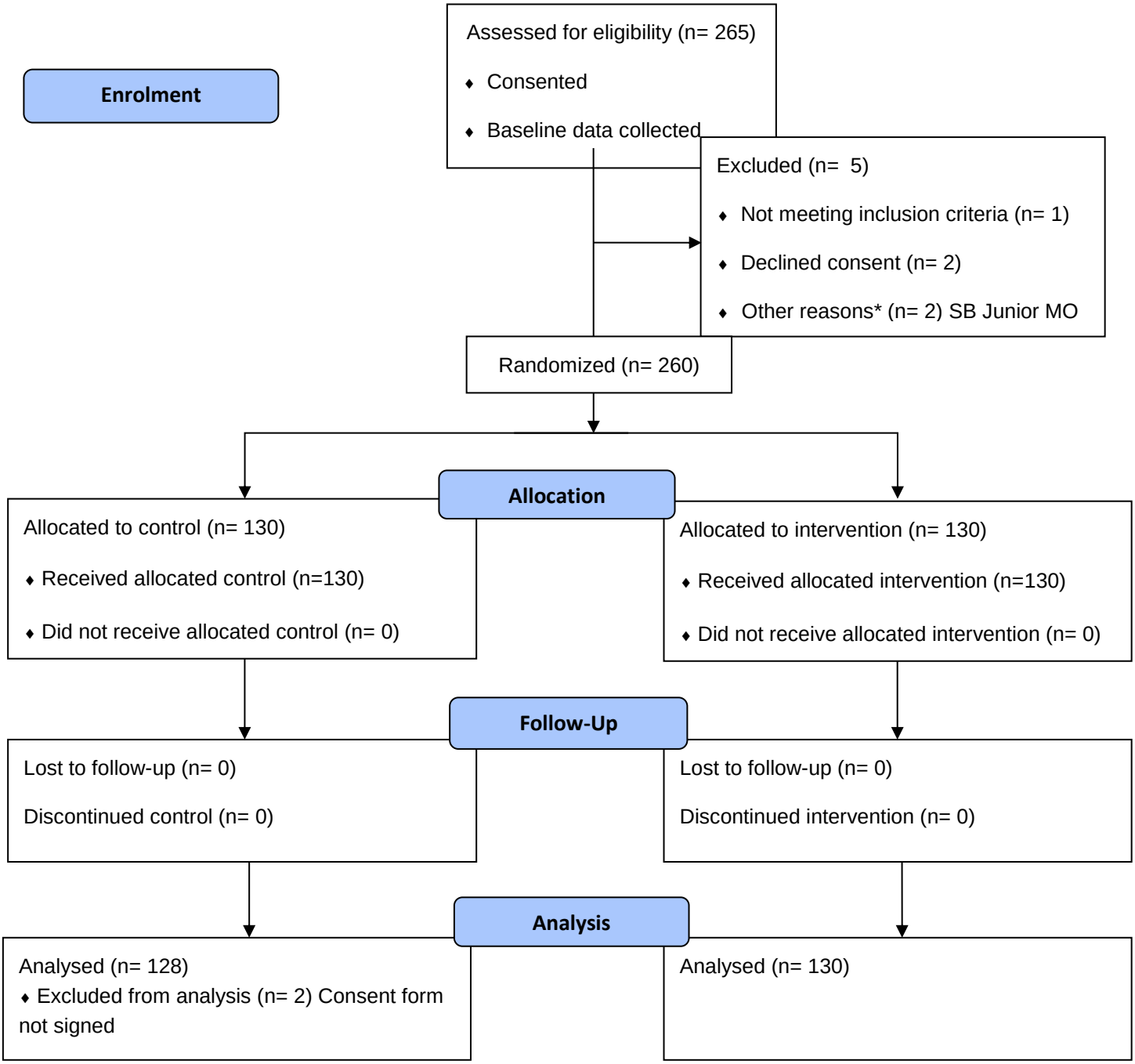
	Standard care (n=128)	NP care (n=130)	P value
Sex			
Male	78 (61%)	69 (53%)	0.20
Female	50 (39%)	61 (47%)	
Age (years)			
Median (IQR)	33 (25.5-43)	30 (25-45)	0.75
Age group			
<25a	30 (23%)	29 (22%)	-
25-34	42 (33%)	48 (37%)	0.62
35-44	27 (21%)	19 (15%)	0.42
45-54	12 (9%)	14 (11%)	0.69
>55	17 (14%)	20 (15%)	0.64
Time of presentation			
08:00- 10:59a	33 (26%)	26 (20%)	-
11:00- 13:59	59 (46%)	53 (41%)	0.65
14:00- 16:59	25 (20%)	34 (26%)	0.17
17:00- 20:30	11 (8%)	17 (13%)	0.15
Mode of transport			
Private car	114 (89%)	109 (84%)	-
AV	4 (3%)	7 (5%)	0.35
Public transport/taxi	10 (8%)	14 (11%)	0.38
Analgesia taken at home			
Yes	46 (36%)	46 (35%)	0.82
No	82 (64%)	84 (65%)	-
Type of analgesia taken			
None	81 (63%)	84 (65%)	-
Simple	22 (17%)	24 (18%)	0.88
NSAID	9 (7%)	10 (8%)	0.89
OPIOID	3 (2%)	2 (2%)	0.63
Other	1 (1%)	1 (1%)	0.98
Unknown	3 (2%)	4 (3%)	0.75

>1 analgesia taken	9 (7%)	5 (4%)	0.28
PS (0)			
Median (IQR)	5 (4-7)	5 (4-7)	0.92
ATS	1 (1%)	0 (0%)	-
2	27 (21%)	21 (16%)	0.36
3	80 (63%)	86 (66%)	0.84
4	20 (15%)	23 (18%)	a
5			

AV- Ambulance Victoria, NSAID – non steroidal anti-inflammatory drugs, PS – Pain score, ATS – Australasian triage scale, [a] Reference group

A total of 265 patients were assessed for eligibility in the study (Figure 1), of which 260 were randomly assigned to either the control or the intervention group. Data from two patients were excluded from analysis due to an incomplete consenting process (n= 2). Data from 258 patients were analysed in the study, with 128 receiving standard ED medical led care and 130 receiving nurse practitioner care. Treatment groups were balanced in respect to all patient baseline demographics (Table 1) and the common diagnostics subgroup classifications of ICD-10-AM (Statistical classification of Diseases and Related Health Problems, 10th Revision, Australian Modification).

Figure 1. Patient flow diagram (CONSORT, 2010).



*During the time the clinical research assistants were completing the randomisation process and assigning the care group, these patients had already been taken into a cubicle and their treatment commenced by other practitioners.

Men (147; 57%) and women (111; 43%) aged 17 – 80 years were enrolled in the study. There were a total of 102 different ICD discharge diagnoses allocated to patients enrolled in the study. The most common diagnoses were open wounds to hand or wrist (n= 19), sprain/strain of the ankle unspecified (n= 13) fractured foot (n= 11) and cellulitis unspecified (n=11). The proportion of patients who self-administered home analgesia overall was 36%. The number of patients who refused analgesia by their care group was 28 and a further 65 patients were not administered analgesia during their ED episode of care (n=93). Representations occurred in 6 (0.5%) of the nurse practitioner group and 1 (<0.1%) in the standard care group. All re-presentations were documented as planned representations and scheduled to return for review in the ED.

Primary outcome

Of all patients, the proportion who received analgesia within 30 minutes from being seen was 49.2 % (n=64) in the NP group and 29.7% (n=38) in the standard group, a difference of 19.5% (95% CI: 7.9-31.2%, p=0.001).

Table 2. Time to analgesia outcomes

Outcome	Standard Care n=128	NP Care n=130	Difference (95%CI)	p-value
Patients given analgesia within 30 minutes of being seen	38 (29.7%)	64 (49.2%)	19.5% (7.9-31.2%)	0.001
Time from being seen to analgesia (Mins) Mean (SD)*	43.0 (35.5)	25.4 (39.2)	17.6 (6.1-29.1)	0.003
Time from being seen to analgesia (Mins) Median (IQR)	37 (23-50)	15 (10-21.5)	22	<0.001
Patients given analgesia within 30 minutes of presentation	2 (1.6%)	20 (15.4%)	13.8 % (7.3-20.4%)	<0.001

**n=89 standard care, n=76 NP care*

Table 3. Secondary outcomes – pain score documentation.

	Standard care n=91	NP care n=82	P values
PS change Median (IQR)	0 (-1, 0)	-0.5 (-3, 0)	0.13
Documented PS (0)*	128 (100%)	130 (100%)	
Documented PS (1)*	91 (71.1%)	82 (63.1%)	
Documented PS (2)*	12 (9.3%)	17 (13.1%)	

**PS (0) recorded at baseline,*PS (1) next recorded PS post PS (0), *PS (2) next recorded PS post PS (1)*

Secondary outcomes

Table 2 and Fig 2 summarise all time to analgesia outcomes.

Figure 2 displays the time to analgesia for all patients using a Kaplan-Meier analysis.

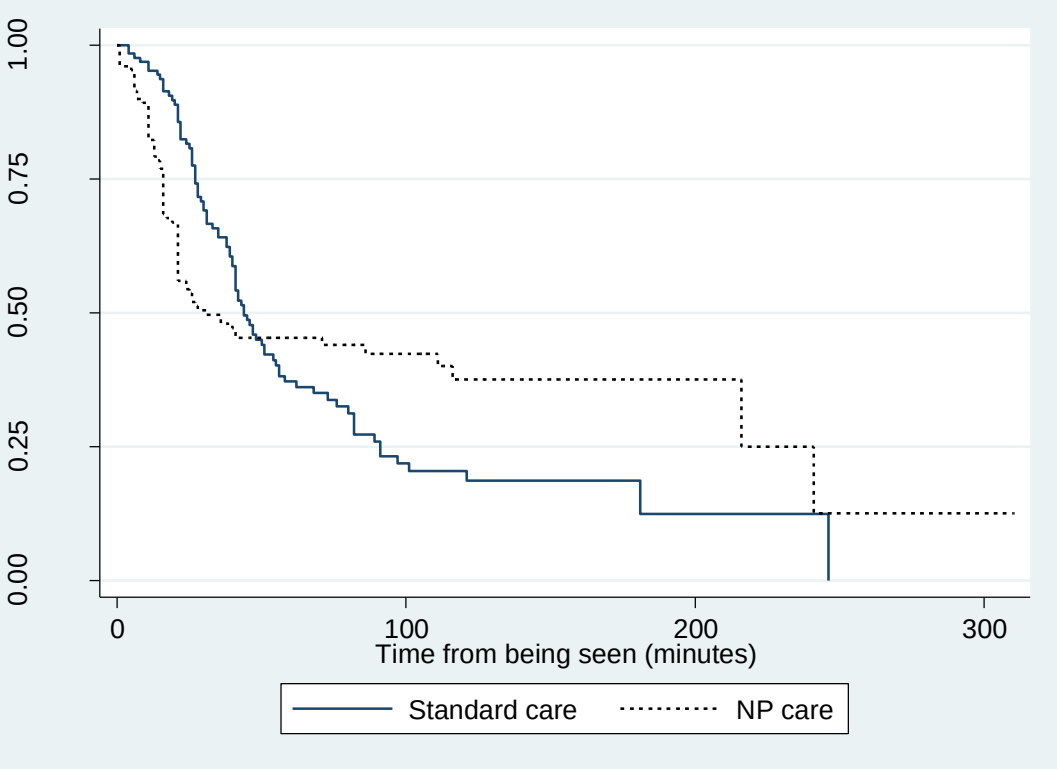


Figure 2: Kaplan Meier Survival Curves showing time from being seen to analgesia by group

Note: logrank test, p=0.82; Wilcoxon (Breslow) test, p=0.02

Of the165 patients who received analgesia, 64 patients (84.2%) received analgesia within 30 minutes in the NP group compared to 38 patients (42.7%) in the standard care group, a difference in proportion of 41.5% (95% CI: 28.3-54.7%, p <0.001).

The first pain score (PS1) documentation rate following being seen was 71.1% (n=91) for standard care and 63.1% (n= 82) for NP care (p=0.17). A subsequent (second) pain score (PS2) was documented in 9.3% (n=12) of standard care patients and 13.1% (n=17) of NP care patients (p=0.35). The median (IQR) change in pain score following being seen was 0 (-1,0) in the standard care group (n=91) and -0.5 (-3,0) in the NP group (n=82)(p=0.13).

DISCUSSION

This randomised controlled trial demonstrated that the nurse practitioner service delivered timely analgesia within recommended national clinical targets more often than standard ED care. Specifically, on the outcome of interest, the proportion of patients with pain receiving analgesia within 30 minutes of being seen was 20% greater when managed by the nurse practitioner group versus the standard care group.

A series of secondary outcomes, examining time to analgesia using various methods, were compared across groups with similar results. The application of a survival analysis approach to further investigate differences in time to analgesia from being seen between the two groups (i.e. the Kaplan-Meier curves) highlighted that the advantage of the nurse practitioner service was most apparent in how quickly analgesia was administered in the first 30 minutes following ED arrival. Traditional tests for a statistically significant difference between the groups are less useful when the curves cross and provided inconsistent results here. Using the log-rank test, no statistical difference in the time to analgesia from being seen between groups was demonstrated over the whole study period. However, the Wilcoxon-Breslow test of the difference in median time to analgesia from being seen between groups was also performed and supported a statistically significant difference. The explanation for this inconsistency is that the log rank test gives more weight to analgesia administered at later time points, whereas the Wilcoxon-Breslow test gives more weight to analgesia administered at earlier time-points.

Time from being seen to analgesia

Time from seen to analgesia is a process measure of ED service delivery and its effectiveness. Previous research[13] demonstrated good reporting of analgesia administration times, where as pain score documentation was very poor. As an important component of quality of care, improvement in the time to receiving analgesia from being seen impacts favourably upon the patient experience and is considered to be clinically efficacious. The National Emergency Care Pain Management Initiative[37] recommend a decrease of at least five minutes in time to delivery of analgesia to be clinically significant. In this study, patients received analgesia 17 minutes sooner if managed by the nurse practitioner service.

Time from arrival in ED to analgesia

Analgesia administration from time of presentation has been investigated previously within ED models of care with patients presenting with migraine, abdominal pain and fractured neck of femurs[16,20]. The time of presentation to analgesia in the literature was reported as ranging from 70- 75 minutes. A similar performance was observed in this study with a low proportion of ED patients receiving analgesia within 30 minutes from presentation. However nurse practitioner service patients were more likely to receive their analgesia within 30 minutes from presentation. These results are consistent with the literature [14,19-22] and demand investigation towards reduction in waiting times for assessment by all ED clinicians.

Pain score documentation

Previous research has shown the documentation of pain scores at triage to be as low as 37% and follow up pain score rates of as little as 33%[14,21]. This study demonstrated a 67% documentation of the first pain score after being seen. Emergency department pain management relies on patients being evaluated on a validated pain assessment tool[16] to guide best practice of analgesic prescribing. Significant improvements in documentation of pain scores can be achieved and have been previously reported[14], but needs to be sustained throughout the ED episode of care. Our results suggest that despite every patient having a documented pain score at baseline, and analgesia being delivered, reassessment of pain intensity was not followed through to disposition and documented. There were only a small percentage of patients who had documented PS after analgesia administration, making it difficult to conduct a meaningful analysis on pain reduction.

Nurse practitioner service issues

This study evaluated nurse practitioner service effectiveness on clinical outcomes directly related to the evaluation of quality of patient care. Our study was unique given that dedicated staff allocated to work in the fast track zone included both standard care and nurse practitioner service and neither group were pulled as a resource for the rest of the department. Consequently we were able to use a standardized comparator and eliminate opportunities for ambiguous observations or threats to validity.

Previously there has been no evaluation of nurse practitioner service effectiveness regarding pain management or the timeliness of analgesic treatment. One previous study had described prescribing practices amongst Australian nurse practitioners but its correlation to best practice management and the ability to meet national standards in the ED setting were not addressed[38,39]. This is the first study to evaluate direct patient clinical outcomes delivered by nurse practitioner services in a robust, well-powered RCT. These results are important as previous studies did not provide rigorous evidence for nurse practitioner clinical effectiveness. This research demonstrates that there exists further scope to optimise the nurse practitioner service model in its ability to delivery analgesia within national benchmarks.

Much of the literature surrounding best practice pain management in the ED suggests the adoption of innovative pain management initiatives to reduce the delay to timely analgesia. Such innovations implemented include nurse initiated pain protocols and a national initiative to improve pain management[14,15,21,30]. Registered nurse initiated analgesia in the ED has been used successfully in reducing time to analgesia for ED patients[17,40]. Initiation of analgesia by nursing staff using a pre-defined protocol, prior to the patient being seen by a medical officer[15], has reported significant decreases in median time to first analgesia dose and the documentation of pain scores[41]. In this study, nurse initiated analgesia protocols were not in practice, but 34 (13%) patients received analgesia prior to being seen by the care group. This was most likely in circumstances where the triage nurse sought authorised clinicians to request analgesia for patients while they waited for their clinician to start their assessment. These patients were included in the analysis as they did proceed to have treatment by the care groups, with assessment and delivery of analgesia required as per usual care delivery.

It is essential in the current ED landscape that service delivery processes are further optimised to augment effectiveness. Enhancing the management process of service delivery, within the ED setting is a potential strategy to achieve best practise pain management. All patients should receive analgesia for their complaint of pain and the efficacy of the treatment should be assessed for improvement in the patients' reported PS. There is room for improvement in both care groups' ability to achieve the national target of analgesia administration within 30 minutes, but further investigation is required to determine how to achieve greater efficiency in delivering timely analgesia.

Evaluating service delivery models that incorporate earlier analgesia to patients during triage, therefore require further exploration. Time mapping to determine inefficiencies from registration, streaming, clinician allocation, ordering analgesia, dispensing and analgesia administration are also required. Enhancement in communication regarding requesting and administration of analgesics between the registered nurse and the medical officer may also require improvement. The process of the medical officers dispensing their own analgesia in the fast track zone could also be one strategy to enhance timely analgesic delivery. A targeted education module and awareness program for all ED staff, aimed at improving ED pain management to obtain best practice is warranted. At the very least, the next major step to reducing pain in ED patients would be to ensure that pain scores are better elicited and documented.

LIMITATIONS

These study findings need to be considered in light of the ED service limitations. While timely analgesia and efficient pain management are important quality indicators for all ED patients, delayed access to ED care[1,42,43] can adversely affect the ability to meet set clinical performance targets. There are many potential factors that can influence the ability to administer analgesia within 30 minutes. Some of the systemic issues might include a lack of inpatient bed capacity resulting in ED overcrowding, patient registration processes, streaming models of care, and the availability and potential for inconsistent practice amongst clinicians. The pragmatic controlled design of this study has attempted to mitigate the potential effect of these issues by directly comparing nurse practitioner service and standard ED care within the fast track service only. There were multiple individual nurse practitioners contributing to the NP service and multiple individual doctors providing the standard care service. It was considered very unlikely that any

individual practitioner would be over-represented in the analysis of effect size; therefore the analysis was conducted on the basis that within each of the care groups the intervention was consistent.

There are features in the intervention and control service delivery models that may have influenced the results. Nurse practitioner service is a hybrid model incorporating both nursing and medical care activities. Consequently, whilst the nurse practitioner is supported by a registered nurse in episodes of care, in regards to analgesia management the nurse practitioner will usually assess the patient, request their analgesia and more often than not, dispense and deliver the analgesia to the patient. Alternatively, standard ED care involves the medical officer assessing the patient, requesting the analgesia and the registered nurse usually conducts the delivery of analgesia. These naturalistic factors were not amenable to being controlled and warrant further exploration. However as is common with pragmatic trials it is difficult to identify which components of the service intervention is directly linked to the outcomes: in this case time to analgesia and effectiveness of reaching national clinical targets.

In this study, the nurse practitioners were experienced emergency nurses that have previously undertaken the necessary educational preparation and accreditation to practice as nurse practitioners. However, they have only been authorised to practice autonomous prescribing of analgesia for a maximum of four years in their nurse practitioner scope of practice. The nurse practitioners may have been more experienced in years of delivering nursing care to patients but had similar prescribing experience to the standard care group.

All patients presenting with pain should have the opportunity to have their pain encounter assessed and managed according to best practice management. Therefore, patients reporting pain (PS >0) were included in this study but there patients who received no analgesia during their episode of care. There were also some patients who refused analgesia in this study. For the purpose of the analysis of the primary outcome, these cases were analysed as not having received analgesia within 30 minutes of being seen.

Local ED policy mandates the documentation of PS for patients presenting to the ED with pain. But pain score documentation after triage is not directed by guidelines and is usually clinician dependent. No strict time periods were set for PS to be documented in this trial. Pain scores that were not recorded were dealt with in the secondary outcome analysis using complete case analysis. Greater documentation of PS post analgesia would have assisted with more rigorous comparison of analgesic efficacy based on changes in PS between care groups.

Generalisability of these results to other ED settings with different patient census and staffing models may be limited and requires further investigation. Medical record documentation and data extraction from the ED Patient information system is prone to misclassification or information bias. Strategies were implemented to reduce bias, as previously published by the authors.

Conclusions

Emergency nurse practitioner service has demonstrated improved time to analgesia and therefore quality of patient care. The nurse practitioner service innovation has demonstrated it can add value to best practice pain management in the ED. In the context of increased health service demand and the need to provide timely and effective care to patients these results will inform evidence based health service planning.

Acknowledgments

The lead research assistant, Arushi Kansal was instrumental in the data transfer process and we appreciate her contribution. The computer generated randomisation schedule was provided by the clinical trial pharmacy at the Alfred Hospital by Pharmacist Anne Mak. The medical students from Monash University and the Alfred Hospital registered nurses who gave their valuable time to act as research assistants, we appreciate. We also acknowledge the patients, family and staff of the Alfred Hospital for ongoing support of clinical research.

Author contributions

NJ, GG and GO were responsible for design and operationalizing the trial, with ethical and governance clearance managed by NJ. NJ and GO were responsible for the statistical analysis and DM was in charge of unblinding the results. AK was solely responsible for all data transfer and verification. NJ and BM were in charge of all research assistants and patient management in

the ED. NJ was responsible for initial drafting and redrafting of the article with critique and editing provided by the whole team.

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6.4 Publication Six- Service level results

Journal of the
American Association of Nurse Practitioners

The effectiveness of emergency nurse practitioners on service indicators in the emergency department– A pragmatic randomised controlled trial.

Natasha Jennings, Glenn Gardner, Gerard O'Reilly and Biswadev Mitra.

American Academy of Nurse Practitioners.

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Google Scholar: 3/20
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6.4.1 Introduction

The previous literature has failed to address the complexity of the NP service as a health services innovation. The pragmatic research design of the RCT has taken into account the challenges of evaluating E-NP service and the results are presented in the following manuscript. Considering, the national clinical indicators for ED service delivery are government mandated and designed to monitor, analyse and evaluate a health service's performance (Department of Health Victoria, 2012). There are defined clinical indicators compiled by the Australian Council of Healthcare Standards (ACHS) to provide clinical perspectives on trends in service and measures to improve quality and safety of patient care. The key service indicators of waiting times, length of stay, unplanned representations, and left without being seen rates are essential to be measured to ascertain the effectiveness of the NPs at the services level. As ED demand continues to raise it often outstrips enhancements in interventions to maintain or improve performance. The ability to

examine NP service benefits upon ED services has implications on other key clinical indicators that can impact not only the ED service but also health service planning (Lowthian and Cameron, 2012). This study aimed to evaluate effectiveness of NP service compared with the standard ED care on key service indicators.

6.4.2 Contribution of authors

The author team was: N Jennings, G Gardner, G O'Reilly AND B Mitra. I am the principal author based on the International Committee of Medical Journal Editors criteria for authorship that includes: substantial contribution to the conception of the review; the acquisition, analysis and interpretation of data for the audit; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (Editors, 2014).

6.4.3 Manuscript copy

Title

The effectiveness of emergency nurse practitioners on service indicators in the emergency department– Secondary outcomes of a pragmatic randomised controlled trial.

Authors

Natasha Jennings, Glenn Gardner, Gerard O'Reilly, Biswadev Mitra.

Abstract

Purpose

The rapid uptake of emergency nurse practitioner service in Australia has outpaced routine evaluation of this service model in terms of safety and quality of care patient outcomes. This study aimed to evaluate effectiveness of nurse practitioner service compared with the standard emergency department medical care on key service indicators.

Data sources

A pragmatic randomised controlled trial was conducted in a major urban emergency department in Australia. Patients were randomly assigned to receive standard emergency department medical care or nurse practitioner care. The outcome measures reported in this analysis were comparisons for key service indicators.

Conclusions

There were 260 patients enrolled in the study, with 128 receiving standard emergency department medical led care and 130 receiving nurse practitioner care. There were no significant differences between the two groups in regards to waiting times, length of stay, numbers of patients who did not wait, patient representations within 48 hours and the utility of evidence based guidelines.

Implications for practice

The impact of nurse practitioner effectiveness on key service indicators demonstrated equivalence with standard emergency department care. This result validates nurse practitioner service in being able to demonstrate comparable outcomes and provide a much-needed evidence base that nurse practitioner service is an integral part of the changing health system reform and innovation.

Trial registration details

Australian and New Zealand Clinical Trials Registry dated 18th August 2013, ACTRN 12613000933752.

Key words

Nurse practitioners, emergency service, quality of health care, randomised controlled trial

Main text of manuscript

Introduction

Measuring the quality of patient care in the emergency department is emerging as one of the most important service indicators in Australian health services today. Emergency departments have seen more than 7% growth in patient presentations over the last 5 years and this has contributed to an ever-growing burden on the delivery of quality patient care (Lowthian and Cameron, 2012). The capacity of emergency departments to deliver timely, high quality and consistent patient care is impacted by the increase in the number and complexity of presentations (Lowthian and Cameron, 2012). Emergency department overcrowding is seen as the greatest single impediment to safe and efficient emergency services in Australia and New Zealand (Cameron et al., 2009) resulting in significantly increased waiting times, adverse events, mortality and hospital length of stay (Forero et al., 2010).

National clinical indicators for ED service delivery are government mandated and designed to monitor, analyse and evaluate a health service's performance (Department of Health Victoria, 2012). There are defined clinical indicators compiled by the Australian Council of Healthcare Standards (ACHS) to provide clinical perspectives on trends in service and measures to improve quality and safety of patient care. The rapid uptake of NP service nationally has outpaced the capacity to evaluate this service model in terms of outcomes related to safety and quality of patient care.

The key service indicators of waiting times, length of stay, unplanned representations, and Left without being seen rates are essential to be measured to ascertain the effectiveness of the NPs at the services level. As ED demand continues to rise it often outstrips enhancements in interventions to maintain or improve performance. The ability to examine NP service benefits upon ED services has implications on other key clinical indicators that can impact not only the ED service but also a whole of hospital service (Lowthian and Cameron, 2012). This research aimed to evaluate effectiveness of NP service compared with standard ED medical care on clinical patient outcomes and key service indicators of waiting times, length of stay, unplanned

representations, and Left without being seen rates. This paper describes the effectiveness results on the service indicators with the clinical patient care outcomes reported in a companion paper.

Methods

In this manuscript, I report comparisons between care groups for the key service indicators: waiting times, length of stay, numbers of patients who did not wait, patient representations within 48 hours and the utilisation of evidence based guidelines.

Waiting time was defined as time in minutes from initial registration until treatment commencement by the care group. Length of stay was defined as the time in minutes the patient spent in the ED from initial registration until time of disposition from the ED. Patents who did not wait were defined as those that were registered and streamed but did not wait for assessment by the treatment group. Among the subgroup of patients who presented with ankle pain, knee pain and burns injury, we aimed to determine the use of evidence based clinical guidelines. The utilization of evidence-based guidelines was defined as being documented in the patients' medical records by the care group. Known guidelines used in this setting were the use of Ottawa ankle and knee rules and a local institution guideline for burns care.

The trial was undertaken in one adult tertiary level four ED with an annual census in 2013 of over 65,000 patients(Department of Health Victoria, 2012). The NPs deliver a hybrid service model, holding both nursing and medical skills and geographically located within the fast track zone, which manages approximately 30% of patient presentations. Fast track services enhance ED care processes in an area designated for timely assessment, treatment and discharge of patients seeking primary care type services for less serious illnesses and injuries(Department of Health, 2014)'(Dinh et al., 2012). The 'fast track' is staffed by NPs between the hours of 0700 and 2330, seven days a week. The NP service model includes assessment and management of patients in Australasian Triage Scale (ATS) categories 2-5(Australian College of Emergency Medicine, 2012a), both independently and collaboratively within this established ED model of care. The streaming nurse directs patients assessed as suitable for fast track care to the zone. The

streaming nurses' decision of where to allocate patients is protocol driven and based on patients' presenting complaints. The study aims, methods and protocol have been previously described(Jennings et al., 2014b). The first patient was enrolled in February 2014.

This study was conducted according to the National Statement on Ethical Conduct in Human Research, 2007 (Council, 2007). Approval was obtained from the relevant University and hospital Human Research and Ethics Committees.

Selection of participants

All patients presenting to the ED with a complaint of 'Pain' and allocated for their episode of care to the 'fast track' zone were eligible for inclusion in the trial. This cohort of patients must have presented to the ED between the hours of 0800- 2030 when both NP and standard care were available and be over 16 years of age. 'Pain' needed to be identified in their streaming description and recorded in the ED patient information system (Cerner Firstnet™). Patients were excluded if their Verbal Numeric Pain Scale (VNPS) was <1 at the point of potential enrolment. Patients who were non-English speaking, had multiple injuries or altered conscious states were excluded from participation in the study. Patients were required to provide written informed consent to participate in the study.

Randomisation

Following collection of baseline data, consenting patents in series were randomly assigned to receive either standard care (control) or NP care (intervention). Randomisation was performed with an allocation sequence of four and generated by computer random number generator and then transcribed into opaque sequentially numbered sealed envelopes. Each envelope contained a card with the allocation group recorded and treatment pack. Allocation adhered strictly to the generated sequence and was maintained. Both participants and treating staff were aware of treatment allocation. The primary investigator was blinded to the allocation groups for analysis of the results. Analysis was undertaken on an intention to treat basis.

Interventions

A medical officer managed patients allocated to the control group with assistance from registered nurses, if required. Medical officers rostered to the 'fast track' zone were emergency medicine registrars with a minimum of 3 years post basic training and were undertaking advanced training towards fellowship of the Australasian College for Emergency Medicine. Medical officers were dedicated to the 'fast track' zone and were required to stay in this zone. Standard ED care was practiced in accordance with usual ED policy with no changes to the model during the study period. The patient was allocated to the 'fast track' zone and the next available clinician commenced the initial assessment.

The intervention group was managed by the NP service. The emergency NP model of care includes assessment and management of patients, including referral directly to other health care providers, prescription of medications, performing interventions, ordering and interpreting diagnostic investigations and admission/discharging autonomy. After initial assessment, NP service commences management of the patient and completes the episode of care. The service is geographically located in the fast track area of the ED. The NP works closely with the registered nurse allocated to the fast track zone, sharing care responsibilities such as collecting graphic observations, administering medications and flow through the area. There were nine nurse practitioners rostered to the fast track zone all accredited and endorsed and holding specialist emergency care qualifications.

Outcome measures

Outcome measures analysed in the study were time to analgesia from presentation, changes in pain scores and documentation of pain scores. In this manuscript, we report comparisons between care groups for the key service indicators: waiting times, length of stay, numbers of patients who did not wait, patient representations within 48 hours and the utility of evidence based guidelines.

Waiting time was defined as time in minutes from initial registration until treatment commencement by the care group. Length of stay was defined as the time in minutes the patient spent in the ED from initial registration until time of disposition from the ED. Patents who did not wait were defined as those that were registered and streamed but do not wait for assessment by the treatment group. Among the subgroup of patients who presented with ankle pain, knee pain and burns injury, we aimed to determine the use of evidence based clinical guidelines. The use of evidence-based guidelines documented in the patients' medical records by the care group was considered utility. Known guidelines used in this setting were the use of Ottawa ankle and knee rules and a local institution guideline for burns care.

Data collection

In order to strengthen methodological rigour, different research assistants undertook each stage of the trial and data entry. Separating the different phases of the study i.e. recruitment and baseline data collection, randomisation (computer generated), outcome data collection, data entry and data analysis (lead researcher), was used as an additional measure to reduce bias. Two data collection forms were developed to collect baseline characteristics and outcome data. The clinical research assistants obtained baseline data directly from the patient. The outcome research assistants collected data from the ED patient information system/electronic heath record that were recorded prospectively during the patients' episode of care.

All data were entered into a Microsoft Excel™ spreadsheet for blinded analysis. To ensure the highest accuracy and quality of data, strategies were used to minimise errors during data processing. A list of all values contained within the variables in the dataset were listed and then crosschecked to determine if there were any responses that were outside these values. Any outliers were verified against the original data forms. Verification entry was undertaken to determine if there were any coding errors related to the miscoding of patients' responses and 10% of all data forms were randomly selected by the lead research assistant to compare the entered data with the hard data collection forms (Kirkwood, 2003).

Statistical analyses

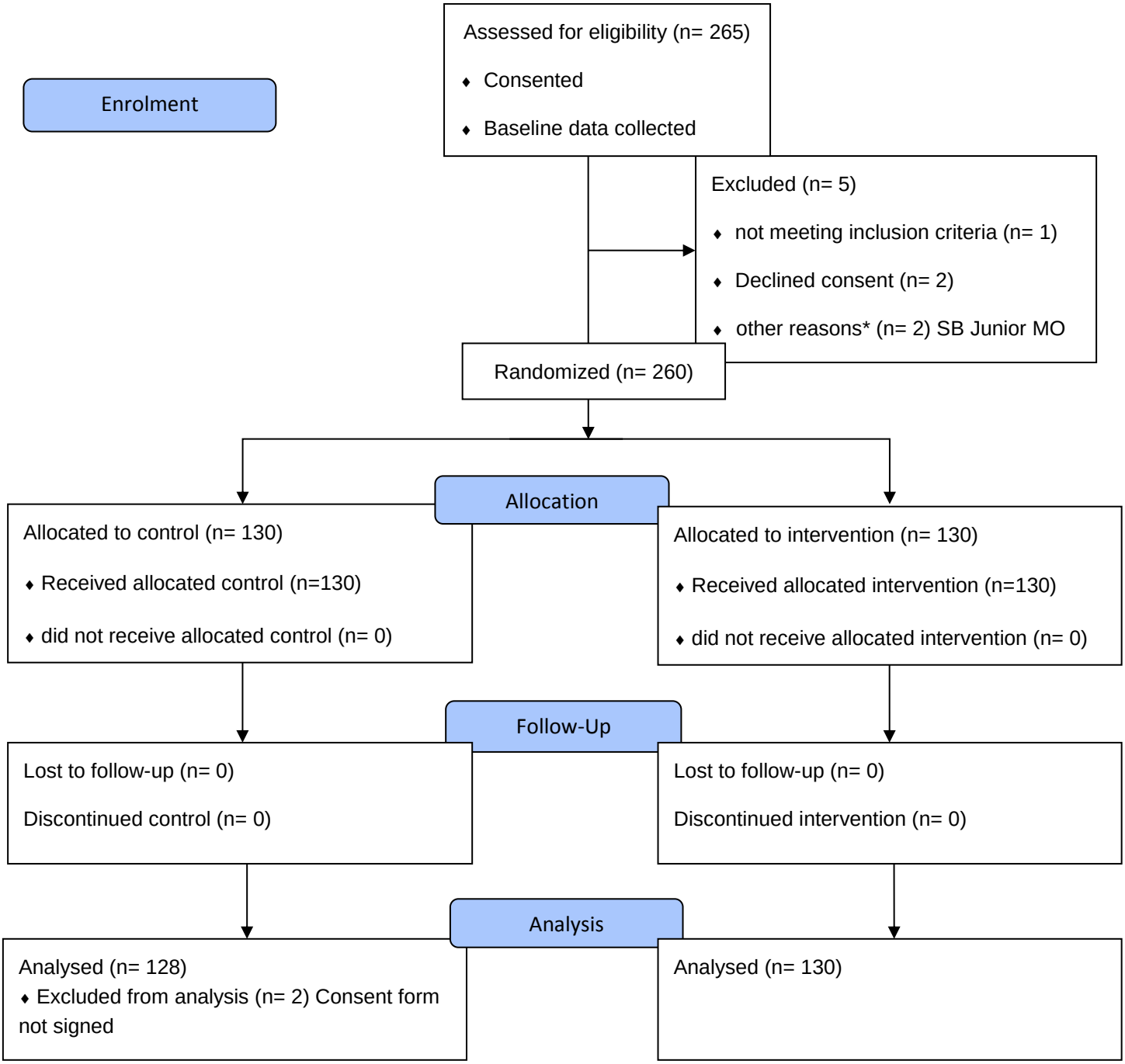
Sample size calculations were based on the primary outcomes of the study and reported in the full methodology of the randomised controlled trial detailed in a companion paper (Jennings et al, 2014). Consequently the sample size was calculated to total 260 patients; 130 patients per arm of the study. The results were analysed using an intention to treat and per protocol analysis.

Our results were normally distributed and continuous variables were presented using the mean (standard deviation). To determine statistical significance, Student's t-test was used to compare two means. A p-value of less than 0.05 was considered statistically significant. All analyses were performed using Stata version 12.0 (Statacorp, College Station, TX, USA).

Results

A total of 265 patients were assessed for eligibility in the study, of which 260 were randomly assigned to either the control or the intervention group. A CONSORT diagram is provided in figure 1. The data from two patients were excluded from analysis due to consent procedures not being fully followed (n= 2) which left 258 patients included in the study, with 128 receiving standard ED medical led care and 130 receiving NP care. Treatment groups were balanced in respect to all patient baseline demographics (Table 1).

Figure 1. Patient flow diagram (CONSORT, 2010).



*During the time the clinical research assistants were completing the randomisation process and assigning the care group, these patients had already been taken into a cubicle and their treatment commenced by other practitioners.

Men (147; 57%) and women (111; 43%) aged 17 – 80 years were enrolled in the study. The majority of patients were represented in the 25-34 years age group. The median pain score on arrival was 5 (4-7) and the most common ATS category seen by both groups was 4 (1-5).

Table 1. Baseline characteristics of all recruited patients

	Standard care (n=128)	NP care (n=130)	P value
Sex			
Male	78 (61%)	69 (53%)	0.20
Female	50 (39%)	61 (47%)	
Age (years)			
Median (IQR)	33 (25.5-43)	30 (25-45)	0.75
Age group			
<25a	30 (23%)	29 (22%)	-
25-34	42 (33%)	48 (37%)	0.62
35-44	27 (21%)	19 (15%)	0.42
45-54	12 (9%)	14 (11%)	0.69
>55	17 (14%)	20 (15%)	0.64
Time of presentation			
08:00- 10:59a	33 (26%)	26 (20%)	-
11:00- 13:59	59 (46%)	53 (41%)	0.65
14:00- 16:59	25 (20%)	34 (26%)	0.17
17:00- 20:30	11 (8%)	17 (13%)	0.15
Mode of transport			
Private car	114 (89%)	109 (84%)	-
AV	4 (3%)	7 (5%)	0.35
Public transport/taxi	10 (8%)	14 (11%)	0.38

Analgesia taken at home			
Yes	46 (36%)	46 (35%)	0.82
No	82 (64%)	84 (65%)	-
Type of analgesia taken			
None	81 (63%)	84 (65%)	-
Simple	22 (17%)	24 (18%)	0.88
NSAID	9 (7%)	10 (8%)	0.89
OPIOID	3 (2%)	2 (2%)	0.63
Other	1 (1%)	1 (1%)	0.98
Unknown	3 (2%)	4 (3%)	0.75
>1 analgesia taken	9 (7%)	5 (4%)	0.28
PS (0)			
Median (IQR)	5 (4-7)	5 (4-7)	0.92
ATS			
2	1 (1%)	0 (0%)	-
3	27 (21%)	21 (16%)	0.36
4	80 (63%)	86 (66%)	0.84
5	20 (15%)	23 (18%)	a

AV- Ambulance Victoria, NSAID – non steroidal anti-inflammatory drugs, PS – Pain score, ATS – Australasian triage scale, [a] Reference group

Outcome measure

Table 2 provides a summary of service outcomes indicators of waiting times and length of stay.

Table 2. Service Outcome indicators

Outcome	*Standard Care N=128*	*NP Care N=130*	*Difference (95%CI)*
Waiting times (Mins) + Mean (SD)	**39.4 (29.4)**	**41.5 (28.2)**	**2.1 (-4.9 to +9.2)**
Length of stay (Mins) + Mean (SD)	**146.7 (75.0)**	**143.5 (63.1)**	**-3.2 (-20.2 to +13.8)**

In the study all patients n=258 waited to be seen by the care groups. The numbers of patients who presented with acute injuries that included burns or to the body regions ankle and knee, contributed to only 15.1 % (n = 39) of all patients. The utility of evidence based guidelines documented in the electronic health record occurred in only 2 patients in the NP group and 0 patients in standard care (see Table 3). The guidelines documented in the electronic records were the clinical decision rules s used for ankle and knee injuries. Representations occurred in 6 (0.5%) of the NP group and 1 (<0.1%) in the standard care group. All re-presentations were documented as planned representations and scheduled to return for review in the ED on consecutive days**.**

Table 3. Utility of evidenced based guidelines

Presenting complaint to body region	*Numbers of patients*	*EBG documented*
Ankle	**29**	**1**
Knee	**8**	**1**
Burn	**2**	**0**

***EBG- evidenced based guideline available**

Discussion

This randomised controlled trial revealed there were no significant differences between the NP and standard care groups in regards to waiting times, length of stay, numbers of patients who did not wait, patient representations within 48 hours and the utility of evidence based guidelines. This demonstrates effectiveness of the NP service compared to standard medical care to assess and manage a defined group of patients presenting with conditions that were able to be managed in a 'fast track' setting.

There is a paucity of evidence using prospective data exploring the impact of NP services on key service indicators in the ED. Waiting time is the key service indicator of ED performance used in our study, and has been well reviewed in the literature. Previous studies have shown NP services appear to have had positive impact on waiting times for patients (Carter and Chochinov, 2007, Considine et al., 2010, Fry et al., 2011, Steiner et al., 2009, Van der Linden et al., 2010, Colligan et al., 2011, Jennings et al., 2008, Dinh et al., 2012) and consequently improve access for patients in several key service indicators. Our findings are consistent with a most recent study (McClellan et al., 2012). , demonstrating similar wait time profiles for patients managed by NP service in comparison to medical officers and extended scope physiotherapists. Older less contemporary studies have shown significant reductions in waiting time for patients managed by the NP service in comparison to the emergency medical registrars (Colligan et al., 2011, Jennings et al., 2008).

It is important to consider why our results are valid and significant to ED service delivery models. The ED landscape is evolving and the delivery of quality patient care is also changing. Lean thinking strategies in the ED have been adopted over the last 5 years analysing the processes of service delivery in the ED (Holden, 2011). Lean strategies premise to maximise efficiency of the ED to improve care processes and patient outcomes. Many strategies have been employed as alternative models of care to improve patient access and flow. Fast tracking, streaming, senior assessment teams, ED short stay units and NEAT targets have all been implemented and analysed as innovative concepts aimed to improve service processes (Holden, 2011(Council of Australian Governments, 2014, Centre for Healthcare Improvement and Research, 2013). As with ED services, emergency NP service has evolved with greater scopes of practice and a hybrid model of care delivery. All waiting times across the ED are improving with the inclusion of these innovative service models so it is difficult to ascertain which strategy is linked more directly to the outcome. Hence, NP service effectiveness on waiting times in the current study reflects the transformation in ED care delivery. Emergency NP services are seeing larger numbers of ED presentations (Jennings et al., 2013, McClellan et al., 2013, Lutze et al., 2011), with more complexity and acuity than previously studied. The study was unable to demonstrate a difference in the service indicators between the two care groups. However this study validates the NP service model as effective and comparable to that of standard care.

Our results for patients who represented to the ED service were consistent with the literature. Nash et al.'s (2006) demonstrated a rate of unscheduled returns for emergency NP service patients of 2.3% compared with 4.2% for the medical patients. Colligan et al. (2010) demonstrated similar figures of 2% for the emergency NP service and 1% for medical registrar patient service. Our study demonstrated less than 1% of patients represented for ED Care, of which all cases were scheduled by the NP service for a follow up care. A review of these patients' medical records concluded they had no primary GP contact and required follow up care arrangements. The NP service demonstrated a holistic approach to the patients care by arranging follow up appointments.

Another indicator of quality patient care and service delivery is the utilisation of evidence-based guidelines to guide delivery of ED care. Research has shown the use of evidence based guidelines in the ED has the potential to impact outcomes related to patient quality of care and service delivery (Stiell and Bennett, 2007). There is limited inquiry into the use of evidenced based practice by E- NP services and there are no other studies for direct comparative analysis. One study (Lambert et al., 1997) found NP services were able to administer drugs according to guidelines with a 94-100% compliance rate and Sakr et al (1999) demonstrated NPs adhered to treatment guidelines more frequently than junior doctors. A comparative analysis of NPs and Senior House Officers (SHO) in the application of the Ottawa ankle guidelines demonstrated that NP patients received appropriate investigations for foot and ankle injuries when using the Ottawa ankle guidelines (Hopkins, 2010). Our study showed no association between NP services utility of EBG compared with that of standard care in the small numbers of patients. This may indicate that both service models did not document the rationale for their clinical decision-making.

Limitations

This study provides valuable findings on service effectiveness comparing two ED treatment groups. As with the pragmatic design of the trial, due to the complex nature of NP service intervention it is difficult to capture all of the confounders that may have influenced the results. This was not an equivalence study and it was not powered to demonstrate a statistical difference for the secondary outcomes measured in the study. Applicability of these results to other ED settings with different patient census and staffing models may be limited and requires further investigations. Medical record documentation and data extraction from the ED information systems can be sometimes prone to misclassification or information bias. Strategies were implemented to reduce bias and verification of data entry and published by the authors (Jennings et al, 2014).

As with all service delivery model evaluations, any process that may enhance efficiency to deliver timely, safe and quality patient care is warranted. The results from this study will be explored further to streamline and add increasing efficiency to the service indicators measured in this study.

The key service indicators of waiting times, length of stay, unplanned representations, and Left without being seen rates are essential to ascertain effectiveness of the NPs at the services level. The ability to examine NP service benefits upon ED services has implications on patient quality of care and the ability to meet national clinical indicator targets. The impact of NP effectiveness on key service indicators demonstrated comparable effectiveness with standard ED care. This result validates NP service in being able to demonstrate comparable outcomes and provide a much-needed evidenced base that NP service is an integral part of the changing health system reform and innovation.

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6.5 Summary

The aim of this research was to evaluate E-NP clinical and service effectiveness, in order to advance knowledge and contribute an evidence base for policy and health service planning. The accepted manuscript***, The effectiveness of emergency nurse practitioner service on timely management of analgesia clinical patient care outcomes – A pragmatic randomised controlled trial,*** and the submitted manuscript, ***The effectiveness of emergency nurse practitioners on service indicators in the emergency department– A pragmatic randomised controlled trial,*** present the synthesis of results from the RCT evaluating E-NP clinical and service effectiveness. These results need to be considered in context of evaluating E-NP interventions. The effectiveness of NP interventions evaluated under this framework were directed at;

- Patient care level
- Services level

Patient care level

The study has demonstrated direct impact on clinical outcomes and quality of patient care. Nurse practitioner service effectiveness demonstrated superior performance in delivery of timely analgesia for ED patients. The E-NP service also demonstrated it can add value to best practice pain management in the ED. As an adjunct to the existing initiatives already available in EDs, this study concludes that NP services can be seen as a further approach to best practice pain management and the ability to reach national clinical performance targets.

Services level

The key service indicators of waiting times, length of stay, unplanned representations, and left without being seen rates are essential to be measured to ascertain the effectiveness of the NPs at the service level. The ability to examine NP service benefits upon ED services has implications on patient quality of care and the ability to improve performance and meet national clinical indicator targets. The impact of NP effectiveness on key service indicators demonstrated equivalence with standard ED care. This result validates NP service in being able to demonstrate sustainability and provide a much-needed evidence base that NP service is an integral part of the health system reform and innovation.

Chapter 7. Discussion and recommendations

7.1 Introduction

Advanced practice roles such as NPs were developed in response to increasing patient demand for services and the changing structure of healthcare systems. The adoption of these roles has steadily increased, particularly in emergency services. Emergency nurse practitioner service effectiveness in Australia has not to date been effectively evaluated in relation to safety and quality of patient care outcomes. Emergency nurse practitioner research has needed to move beyond retrospective, qualitative research to produce high quality evidence of efficiency, productivity and clinical effectiveness for patient outcomes for the role to be sustainable into the future. The research developed and reported in this thesis brings new knowledge and reliable evidence to the contribution of a health service innovation. This research is the first robust and rigorous pragmatic RCT to provide evidence of E-NP service effectiveness related to patient clinical and service outcomes. The research involved participants from an urban ED setting with a well-established E-NP service model. The findings from this research will provide evidence across like settings and also have applicability for the international audience seeking evidence of the effectiveness of E-NP services at the patient and health services levels.

The aim of this research was to evaluate E-NP clinical and service effectiveness, in order to advance knowledge and contribute an evidence base for policy and health service planning.

The overall body of inquiry reported here was guided by four statements;

1. Establishing the current evidence surrounding E-NP service effectiveness in relation to safety and quality of patient care outcomes.

2. Developing a clinical profile into E-NP service at the ED setting

3. Determining an appropriate methodology to evaluate E-NP service

AND

4. Conducting a pragmatic randomised controlled trial of E-NP service effectiveness on outcomes at the patient and services level.

This chapter will address each question systematically.

7.2 Establishing the current evidence surrounding E-NP service effectiveness in relation to safety and quality of patient care outcomes

Exploring E-NP service effectiveness in relation to safety and quality of patient care required a literature review on the initial development of E-NP roles from both a local and international context. A review of the international literature found numerous descriptive studies, some observational designs and four RCTs that investigated the NP role in the ED setting (Jennings et al., 2014a). The literature dated back to 1967 and the last RCT was conducted in 2002. The RCTs based in the UK, compared E-NPs with traditional medical models of care. These RCTs had many limitations: including lack of operational definitions used to describe the role, different models of ED care, less than robust methodologies and limited application to the Australian ED setting.

The literature review identified a significant gap in the evidence evaluating the effectiveness of E-NP service on outcomes, quality of patient care and service responsiveness within Australia and abroad. This paucity of research informed the development of a robust strategy to review the literature and critically analyse the research to provide context for developing a clinical inquiry, namely:

What outcomes were associated with patient quality of care and service delivery?

How these outcomes were measured and are they consistent with contemporary ED service delivery?

A systematic review (Publication 1) with narrative findings was conducted (Jennings et al., 2014a). The outcomes of waiting times, patient satisfaction, cost effectiveness and quality of care were identified as key components of measures of patient quality of care and service effectiveness in the literature. The systematic review research findings recommend that E-NP services impact:

- Patient satisfaction and waiting times positively
- Cost effectiveness (shown to be equal to that of other health professionals in regards to soft tissue management)
- Overall quality of care (higher with E-NP service)

The review also highlighted several important issues regarding the evidence reported in the literature:

- Lack of robust and rigorous level one evidence
- Limited application to the Australian contemporary ED landscape
- The need for E-NP service has changed from filling service gaps to service issues related to overcrowding, ED demand and national performance targets

The systematic review has confirmed a limited amount of research evaluating E-NP service effectiveness. Previously, systematic reviews undertaken by Carter et al (2007) and Wilson et al (2009) are outdated and not commensurate with ED service delivery changes in the context of health services reform. Previously E-NP service evaluations were based on services introduced to address service gaps in primary healthcare. In contemporary EDs, E-NP services have been incorporated into ED models of care due to a myriad of other service issues such as overcrowding, increased demand and the challenges of meeting performance targets (National Health Performance Authority, 2013). Hence an inquiry into E-NP service effectiveness in the

current context needed to be established to provide a baseline foundation on which to build this and future research.

This systematic review is now the most up to date information on the state of the science reporting evaluation of E-NP service effectiveness.

7.3. Developing a clinical profile into E-NP service effectiveness

There were several important issues raised from the systematic review that highlighted the importance of this research as a body of work for the evolving science exploring NP service outcomes. This research was the first known work to evaluate direct clinical outcomes and effectiveness of E-NP service at both the patient and services level.

The robust review of the evidence was used to guide the next necessary steps in developing a clinical profile of E-NP service effectiveness at the research setting. The systematic review identified the outcomes of waiting times, patient satisfaction, cost effectiveness and quality of care as key components of service effectiveness. The need for sound baseline and preparatory work was identified to answer the following questions:

What is the current service profile of E-NPs?

What are the current constraints to service delivery in the ED?

What impact does the E-NP service have on patient quality of care and service responsiveness?

There are many descriptive studies highlighting the service profile of E-NP service within Australian EDs (Jennings et al, 2008; Considine et al, 2006). The most common profile described in the literature concentrates on service provision related to patient care of minor injuries and illness in a fast track model (Jennings et al., 2008, Lowe, 2010; Wilson et al., 2008). This research had established E-NP services to have significant impact on waiting times (Carter et al., 2007, Considine et al., 2010, Fry et al., 2011, Steiner et al., 2009, Van der Linden et al., 2010,

Colligan et al., 2011, Jennings et al., 2008 and Dinh et al., 2013) and consequently improved patient service indicators.

The ED setting is a dynamic and major component of Australia's emergency healthcare system. In the current 10 year context, Australian public EDs have seen more than 37% growth in demand over the last decade (FitzGerald et al., 2012) and this has contributed to an ever-growing burden on the delivery of quality patient care. The ability to deliver timely quality patient care in the ED is impacted by increasing numbers of patients requiring emergency care with greater complexity of healthcare needs. The increasing incidence of chronic disease in the community, reduced access to primary healthcare and fewer general practitioners have also contributed to increased demand in ED services (Australian Health Workforce Advisory Commitee, 2006, Sprivulis et al., 2006, Fatovich and Hirsch, 2003).

Emergency nurse practitioner service had been viewed as one potential solution to this increased demand and overcrowding in the ED and had been employed to improve service indicators such as access, efficiency and quality of patient care (Wilson et al., 2008). Timely and effective delivery of analgesia for patients presenting to the ED with pain is an important component of quality of care mandated by national clinical standards (Doherty et al, 2013). The Australian Council of Healthcare Standards uses these clinical indicators to measure health service performance. The Australian College for Emergency Medicine and the College of Emergency Nursing Australia acknowledge pain management as a fundamental component of quality care for ED patients (ACEM, 2009). Previous literature suggest that a lack of timely and effective analgesia in the ED has been negatively associated with longer patient stays in hospital, greater adverse events and poor quality of service (Cameron et al, 2009, Sprivulis et al, 2006, Lowthian and Cameron, 2012). Considering acute pain is the most common reason for patients presenting to the ED (Kellly and Gunn., 2008, Pines., 2008) it became apparent to evaluate pain and timely analgesia as a clinical outcome would achieve the aim of this research. In previous studies describing analgesia prescribing practices among Australian NPs, there has been no analysis of pain management or the timeliness or effectiveness of analgesic prescribing (Dunn et al., 2010, Buckley et al., 2013). Hodges et al, (2011) briefly explored the role of the advanced clinical

nurse (ACN) and the effect on time to analgesia as an indicator of patient quality of care and service responsiveness. The ACN role was a precursor to an E-NP role with a differing scope of practice and credentialing process, compared with the authorised NP role. Hodges et al (2011) results suggested this role was unable to be generalised to the E-NP role due to the fact it was not an E-NP role. As a result, there was no evidence base to add weight to the effectiveness of E-NP service impact on pain management and timely analgesia outcomes.

The preparatory work contained two distinct and very important components to provide a robust platform for the research. The initial preparatory work undertaken in study one (Publication 2) was conducted to establish baseline characteristics of the patient cohort serviced by E-NPs in the naturalistic ED setting. This work was used to inform decisions about the research hypotheses to be generated for the pragmatic RCT. The retrospective audit of E-NP service profile was essential to ensure the research design elements were built upon contemporary data, well considered, and supported careful planning.

The pilot study was the second component of the preparatory work (Publication 3) and evaluated the outcome measures of time to analgesia and national targets for timely administration in the ED setting. These results demonstrated times to analgesia for patients from initial presentation were long but consistent with the published evidence. However, times to analgesia after assessment by the E-NP service were substantially better. This study reinforced the importance of timely and effective delivery of analgesia for patients presenting to the ED with pain. It demonstrated that compliance with the national clinical indicators as a measure of quality of care for E-NP service had opportunities for improvement.

The preparatory work, study one and the pilot, provided the essential ingredients for informing the design of the research for the pragmatic RCT. Each component of the preparatory work was carefully planned to enhance the reliability and validity of the main research design. The preparatory research findings proceeded to set the foundation for the evaluation of the E-NP service effectiveness on outcomes focussed at the patient and service levels.

7.4. Determining an appropriate methodology to evaluate E-NP service

The Australian healthcare landscape is currently undergoing major health service and workforce reform (Council of Australian Governments, 2011). This in turn called for an appropriate research approach to conceptualise and focus on how different workforce models can achieve improvements in healthcare delivery and outcomes. This research developed through a thorough understanding of the existent literature and required a guiding methodology to provide the framework to investigate the relationship between E-NP service, its context and outcomes (Minichiello et al., 2004).The uniqueness of this research required a particular methodological approach taking into consideration three key essential elements of E-NP service:

- Application of health services research as a guiding principle
- NPs as a service innovation
- Evaluation of complex interventions

Previous evaluations of complex interventions have been undertaken in different settings to include interventions based around end of life care, diabetes education and teaching programmes, infant feeding and preventative programmes for cardiovascular disease (Bradley et al., 1999, Muhlauser and Berger, 2002, Higginson et al., 2013, Lakshman et al., 2014). Evaluating E-NP service was going to be methodologically challenging, as there were limited previous studies to adapt protocols or gain insight into confounders or limitations. This research was breaking new ground in evaluating the effectiveness of E-NP service interventions.

Lakshman et al (2014) utilised the MRC framework to guide the development and evaluation of an intervention to prevent obesity. Their research found that in addition to informing development of their specific intervention, the conceptual framework also helped to build a generalisable evidence base for future research of the intervention. Similarly, this research identified the pragmatic RCT approach offered an unique understanding of the E-NP service in its naturalistic setting and has also provided a contemporary evidence base that E-NP service is sustainable and an integral part of health system reform.

The results of this research have demonstrated utility of health services research, embracing evaluation of a complex intervention using a conceptual framework. The MRC guidance on methods of evaluating such interventions was adapted to fit the uniqueness of E-NP service (Craig et al., 2008). The conceptual framework guided the research design and the research demonstrated success in the effectiveness of evaluating the intervention. The conceptual framework has not been applied previously to any research evaluating E-NP service effectiveness. This research will now frame a new approach to the evaluation of NP service outcomes, specifically targeting clinical effectiveness. This framework also makes a contribution to the evolving area of health services research and evaluation of health service innovations.

7.5. Conducting a pragmatic randomised controlled trial to produce evidence of E-NP service effectiveness on outcomes at the patient care and services level.

The conceptual framework described in Chapter Four informed the design elements of this pragmatic RCT. The pragmatic RCT approach combined traditional randomised controlled trial elements with pragmatic features of everyday applicability to provide a balance of methodologies. This design ensured a broad spectrum of patient outcomes would be measured to compare effectiveness of interventions in everyday practice at both the patient care and services level. In order to take into consideration the complexity of evaluating E-NP service, a protocol for the pragmatic RCT was developed and published (Publication 4). These results will attempt to provide a baseline for the evolving science of health services research of clinical intervention models related to E-NP services.

The results from the pragmatic RCT have been evaluated in line with the conceptual framework in two distinct areas, taking into consideration the complexities of evaluating E-NP service. Effectiveness of E-NP service was evaluated at both the patient care and services level. The effectiveness of E-NP service on the delivery of timely analgesia as a patient clinical outcome has previously only been evaluated by a small retrospective chart review (Jennings et al., 2014). Previously there has been no evaluation of NP service effectiveness regarding pain management or the timeliness of analgesic treatment in comparison with standard ED care. Our results showed E-NP service effectiveness was demonstrated through superior performance in delivery of timely

analgesia for ED patients when compared with standard ED care (Publication 5); both clinically and statistically significant results were demonstrated. The research evaluated NP service effectiveness on clinical outcomes directly related to the evaluation of quality of patient care in direct comparison with standard ED care. This is the first study to evaluate direct patient clinical outcomes delivered by NP services in a robust, well-powered RCT. Our results are important as previous studies did not provide rigorous evidence for NP direct patient clinical effectiveness or take into consideration the complexity of the interventions.

It is essential in the current ED landscape that service delivery processes are further optimised to augment effectiveness. Enhancing the management process of service delivery, within the ED setting is a potential strategy to achieve best practise pain management. The main research results show there is room for improvement in E-NP service and standard care groups' ability to achieve the national target of analgesia administration within 30 minutes, but further investigation is required to determine how to achieve greater efficiency in delivering timely analgesia. Enhancing service deliveries that can incorporate earlier analgesia to patients require further exploration.

The main research also evaluated key service indicators of waiting times, length of stay, unplanned representations, and left without being seen rates, all of which are essential to be measured to ascertain the effectiveness of E-NPs at the service level. The ability to examine NP service benefits upon ED services has implications on patient quality of care and the ability to meet national clinical indicator targets. The impact of NP effectiveness on key service indicators demonstrated equivalence with standard ED care (Publication 6). The systematic review and previous studies have shown NP services to have a positive impact on waiting times for patients (Carter et al., 2007, Considine et al., 2010, Fry et al., 2011, Steiner et al., 2009, Van der Linden et al., 2010, Colligan et al., 2011, Jennings et al., 2008 and Dinh et al., 2013, Jennings et al, 2014) and consequently improve access for patients in several key service indicators. Our findings demonstrate similar wait time profiles for patients managed by the E-NP service in comparison to medical officers. Previous studies have shown significant reductions in waiting time for patients managed by the NP service in comparison to the emergency medical registrars (Colligan et al 2011, Jennings et al, 2008).

As already mentioned, the contemporary ED setting is dynamic and attempts to deliver services mandated by national time-based performance targets. The ED landscape is evolving and the delivery of quality patient care is also changing. Lean thinking strategies in the ED have been adopted over the last 5 years analysing the processes of service delivery in the ED (Holden, 2011). Lean strategies promise to maximise efficiency of the ED to improve care processes and patient outcomes. As with ED services, E-NP service has evolved with greater scope of practice and a hybrid model of care delivery. Service indicator benefits have previously been evaluated in the context of the role being used to address service gaps rather than delivery of service issues. Emergency nurse practitioner service effectiveness on waiting times in the current study reflects the transformation in ED care delivery. Emergency nurse practitioner services are seeing larger numbers of ED presentations (Jennings et al, 2013, McClellan et al, 2013, Lutze et al, 2014), with more complexity and acuity than previously studied. ED service issues such as increased ED demand, overcrowding and access have played a major role in the expansion of E-NP services. This study validates the E-NP service innovation as efficient and comparable to that of standard care in the current contemporary ED setting.

7.6 What is it about the NP model that makes it more effective than standard ED care?

What makes the NP model more effective in the delivery of timely analgesia and how does the clinical decision making underpinning the NP model of care attribute to this unique effectiveness of service delivery? The contribution of NP service to the quality and effectiveness of healthcare is unique. The hybrid nature of the NP model is designed to provide a reformative approach to delivering high quality, patient-centred, timely, efficient and equitable healthcare for a new generation of health care consumers. The NP model is anchored in the core professional values and approach to clinical care of advanced nursing service with its focus on holistic patient-centred care. This is combined with a legislated framework that allows extensions to this practice and increased levels of autonomy. Consideration of the nature of practice in different provider models can inform an understanding of the study results relating to the difference in delivering timely analgesia.

Traditionally, the medical model has been focussed on the physical and biological aspects of the patient's disease process or acute condition, using a deductive approach to clinical reasoning (Kitson et al., 2012). Whereas, the nursing model is focussed of how the patient responds to the physical and biological aspects of disease or injury concentrating on the health and well-being of the patient and their family. Uniquely, the NP model is an integrative model that incorporates both the medical and nursing models, but focuses on the human response of the patient and their family (Carryer et al., 2007). This holistic approach is focussed on the treatment of the human response to the physical and biological aspects of the disease and its prevention.

In this research clinicians from both provider models treated the ED patient with an acute presentation of a painful complaint and there were disparate results in the timeliness of analgesia. The NP response time to administering analgesia was significantly lower than that of medical clinicians. This difference may well be related to the nursing element of NP service that distinguished the aspects of clinical care that are otherwise common to both provider models. If we can identify and measure this nursing element of the NP model of care, research can be

conducted across all areas of NP scope of practices. Further research is needed to test this hypothesis.

7.7 Limitations

The pragmatic randomised controlled trial design was designed to reduce bias, limit confounders and increase validity of the research. However with all studies there are some limitations. The research findings need to be considered in light of the ED service limitations and evaluations of effectiveness. While timely analgesia and efficient pain management are important quality indicators for all ED patients, delayed access to ED care (Lowthian and Cameron, 2012, Asaro and Boxerman, 2007, Huang et al, 2010) can adversely affect the ability to meet set national clinical performance targets. There are many potential confounders that influence ability to administer analgesia within 30 minutes. Some of the systematic confounders include access block, overcrowding, patient registration processes, streaming models of care and clinician availability. The pragmatic controlled design of this study has attempted to mitigate these challenges by directly comparing NP service and standard ED care within the fast track service only.

In this context there are features in the intervention and control service delivery models that may have influenced the results. NP service is a hybrid model incorporating both nursing and medical care activities. Consequently, whilst the NP is supported by a registered nurse in episodes of care, in regards to analgesia management; the NP will usually assess the patient, request their analgesia and more often than not, dispense and deliver the analgesia to the patient. Alternatively, standard ED care involves the medical officer assessing the patient, requesting the analgesia and the delivery of analgesia usually augmented by the registered nurse. These naturalistic factors were unable to be controlled and warrant further exploration. However as is common with pragmatic trials, it is difficult to identify which components of the service intervention is directly linked to the outcomes, in this case, time to analgesia.

A local ED policy mandates the documentation of pain score for patients presenting to the ED with pain. Pain score documentation after streaming is not guidelined and is usually clinician dependent. No strict time periods were set for pain score to be documented in this trial. As all treating clinicians were unaware of the primary outcomes of the trial and usual clinical practice was adhered to, this was a limitation of the trial. Greater documentation of pain score post analgesia would have assisted with more rigorous evaluation of the comparison of analgesic efficacy based on changes in pain score between care groups. Generalisability of these results to other ED settings with different patient census and staffing models may be limited and requires further investigations.

7.8 Summary

The pragmatic RCT evaluating E-NP clinical and service effectiveness research provides an evidence base to advance knowledge and contribute an evidence base for policy and health service planning. This research will also assist in guiding healthcare leaders, policy makers and clinicians in the reform of emergency service provision. In the context of increased health service demand and the need to provide timely and effective care to patients, these results will assist in best practice pain management for ED patients. As with all service delivery model evaluations, any process that may enhance efficiency to deliver timely, safe and quality patient care is warranted. Our results showed E-NP service effectiveness was superior in the delivery of timely analgesia for ED patients compared with standard ED care. Emergency nurse practitioner service has demonstrated direct impact on clinical outcomes and the quality of patient care. As a health service innovation, E-NP service has demonstrated it can add value to best practice pain management in the ED. The findings suggest that further high quality research is required for comparative measures of clinical and service effectiveness of E-NP service. The impact of E-NP effectiveness at the patient and service level is summarised below:

Patient care level

- First research to undertake a hybrid pragmatic RCT design to evaluate outcomes related to E-NP service clinical outcomes.
- Superior performance in delivery of timely analgesia for ED patients both clinically and with statistically significant results.
  - If the patient received analgesia within 30 minutes they were more likely to have been seen by the E-NP service.
  - 64 patients (84.2%) received analgesia within 30 minutes in the NP group compared to 38 patients (42.7%) in the standard care group, a difference in proportion of 41.5% (95% CI: 28.3-54.7%, $p < 0.001$.).
  - Our results demonstrated that patients received analgesia 17 minutes sooner if managed by the E-NP service.

Services level

- Emergency nurse practitioner effectiveness on key service indicators demonstrated equivalence with standard ED care.
- The research has also developed a conceptual framework that can be used to guide future evaluations of interventions within health service research.
- This result validates NP service in being able to demonstrate comparable outcomes and is an integral part of the changing health system reform.
- This result validates NP service to demonstrate sustainability and provide a much-needed evidenced base.

This research has demonstrated the effectiveness of E-NP service at both the patient and services level. As health services continue to struggle to meet growing demand and increasing cost this is valuable and timely information. Workforce reform is on the agenda of governments but to date the evidence to support innovative models to restructure service teams has been weak. This research provides the basis to inform health service planning and innovative health workforce models. Emergency nurse practitioner service is safe, clinically effective and has a positive impact of ED service indicators and thus will be a driving influence on the capacity of ED services to meet health care consumer demands.

7.9 Recommendations

The following recommendations from the research are:

1. Processes need to be adopted for EDs to further optimise E-NP service delivery models and other roles to meet quality patient indicators, specifically related to management of pain.
2. The findings from this study need to be implemented at the ED setting and disseminated to our colleagues, clinicians, healthcare directors and policy makers.
3. ED clinicians need to utilise and document the use of evidence-based guidelines.
4. Clinicians, healthcare directors and heath policymakers must collaborate to enhance management processes of service delivery to achieve best practice pain management in the ED for all clinicians.
5. Researchers will be able to draw upon the template of the methodological approach used in this research to evaluate E-NP service in other areas of clinical patient outcomes.
6. The research provides the contemporary evidence that E-NP service is sustainable and an integral part of health system reform.

7.10 Future research

This research provides an evidence base for E-NP clinical and service effectiveness. Further studies are required to build upon and extend this new evidence to influence practice change in relation to pain management and other common presentations to the ED. Continuing to evolve the area of health services research and NPs will be the focus. This research can inform methods for much needed evaluation of other innovative health service delivery models such as expanded scope physiotherapists and advanced practice paramedics. As with all service delivery model evaluations, any process that may enhance efficiency to deliver timely, safe and quality patient care is warranted. The results from this study will be explored further to streamline and add increasing efficiency to the service indicators measured in this study. Finally, in depth investigation of the clinical service capacity of E-NPs is warranted to optimise the scope of practice potential of nurse practitioner roles.

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Appendices List

Appendix A: Audit 1 Ethics Approval

TheAlfred

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 361/12

Project Title: Evaluating patient presentations for care delivered by Emergency Nurse Practitioners: A retrospective review of 12 months

Principal Researcher: Ms Natasha Jennings

was considered for Low Risk Review and ***APPROVED*** *on* **8/8/2012**

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report on the anniversary of approval and on completion of the project.

Approval covers the project as described in the application (including any modifications made prior to approval). Low Risk projects are subject to audit and ethical approval may be withdrawn if the project deviates from that proposed and approved.

SPECIAL CONDITIONS

None

SIGNED:

R Frew
Secretary, Ethics Committee

Please quote project number and title in all correspondence

Appendix B: Audit 2 Ethics Approval

TheAlfred

Ethics Committee

Certificate of Approval of Amendments

This is to certify that amendments to

Project: **506/13 A randomised control trial evaluating outcomes of emergency nurse practitioner service.**

Principal Researcher: **Professor Glenn Gardner**
Student Researcher: **Mrs Natasha Jennings**

Amendment:
Retrospective audit of nurse practitioner (NP) cases before proceeding with the randomised controlled trial

have been approved in accordance with your amendment application dated **24-Jan-2014** on the understanding that you observe the National Statement on Ethical Conduct in Human Research.

It is now your responsibility to ensure that all people associated with this particular research project are made aware of what has actually been approved and any caveats specified in correspondence with the Ethics Committee. Any further change to the application which is likely to have a significant impact on the ethical considerations of this project will require approval from the Ethics Committee.

Chair, Ethics Committee (or delegate) Date: **5-Feb-2014**

R Frew
Secretary, Ethics Committee

Appendix C: RCT Trial Registration

-----Original Message-----

From: info@actr.org.au [mailto:info@actr.org.au]

Sent: Fri 8/23/2013 3:12 PM

To: Jennings, Natasha

Subject: Your ACTRN (registration number): ACTRN12613000933752

Dear Natasha Jennings,

Re: To measure the effectiveness of Emergency nurse practitioners on service and quality of patient care outcomes for patients in the Emergency department compared with standard emergency medical care.

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12613000933752

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12613000933752.aspx

Date submitted: 16/08/2013 11:32:55 AM

Date registered: 23/08/2013 3:12:30 PM

Registered by: Natasha Jennings

If you have already obtained Ethics approval for your trial, could you please send the ANZCTR a copy of at least one Ethics Committee approval letter? A copy of the letter can be sent to info@actr.org.au (by email) OR (61 2) 9565 1863, attention to ANZCTR (by fax).

Please be reminded that the quality and accuracy of the trial information submitted for registration is the responsibility of the trial's Primary Sponsor or their representative (the Registrant).

The ANZCTR allows you to update trial data, but please note that the original data lodged at the time of trial registration and the tracked history of any changes made will remain publicly available.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,

ANZCTR Staff

T: +61 2 9562 5333

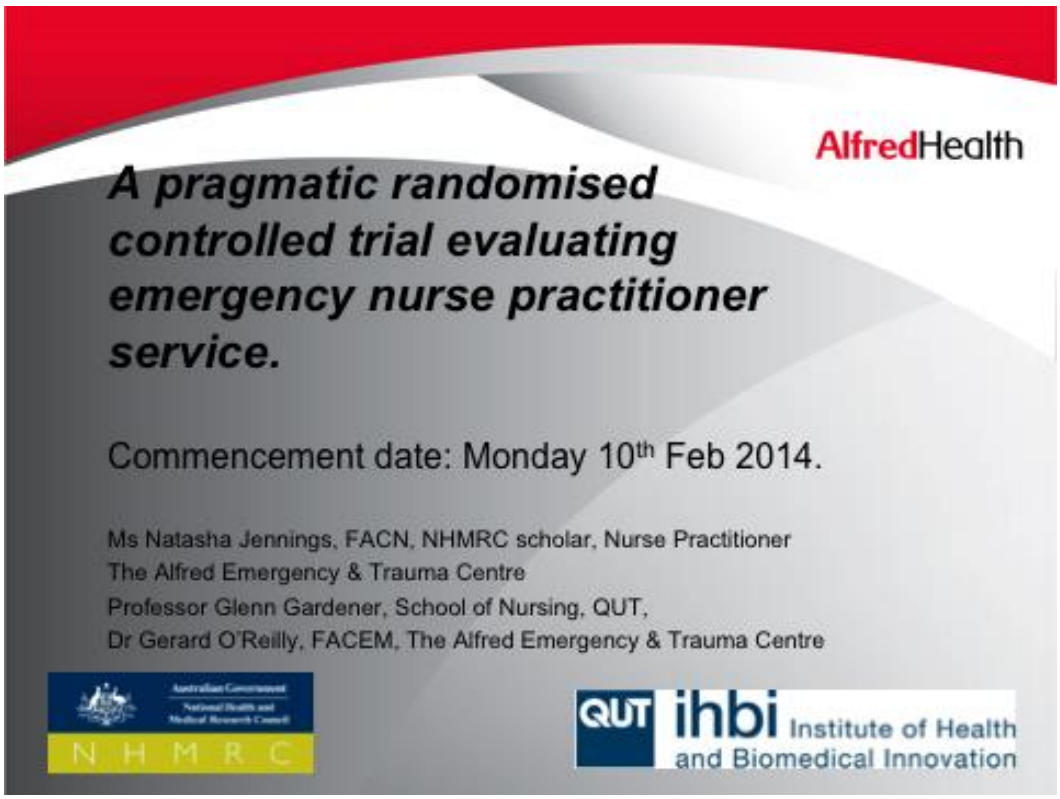
F: +61 2 9565 1863

E: info@actr.org.au

W: www.ANZCTR.org.au

Appendix D: EOI for RAs

Appendix E: RA Training Manual



AlfredHealth

Aim: To evaluate emergency nurse practitioner service effectiveness on outcomes related to qualities of care & service responsiveness.

Background: The delivery of quality patient care in the emergency department (ED) is emerging as one of the most important service indicators to be measured in health services today. Increasing service pressures in the emergency setting have resulted in the adoption of service innovation models; the most common and rapidly expanding of these is the emergency nurse practitioner (E-NP). The rapid uptake of E-NP service in Australia has outpaced the capacity to evaluate this service model in terms of outcomes related to safety and quality of patient care. Our study aims to evaluate an intervention designed to improve the provision of quality care and health service performance.

AlfredHealth

Methods: This trial will be a definitive prospective randomised controlled trial, which will examine the impact of E-NP service on key patient care and service indicators. Eligible & consenting ED patients allocated to the fastrack zone will be randomised to either the control or intervention group.

The study control will be standard ED care, which is operationally defined as medical officer managed care with assistance from registered nurses. The intervention to be evaluated in this research will be E-NP service.

A clinical research assistant will perform all consenting, randomization and data collection. No change in practice from treating clinicians is required.

Sample size: 130 patient per arm estimated recruitment time 6 weeks

Frequently asked questions

AlfredHealth

How do I know if my patient is in the trial? *A large colored sticker will be placed on the patients red folder and in the front sleeve of the folder.*

Do I need to change the way I treat patients? *No. Continue to care for patients in the same manner as you currently do.* Please make sure you document pain score prior to administering medications and 30 minutes post analgesia as per hospital policy.

Do I need to collect any data or fill out any forms? *No. A clinical research assistant will be on site and based in the fast track office who will consent, randomise and complete all data collection forms.*

Will the results be identifiable? *Clinicians will be compared as a group and no individual clinicians will be able to be identified.*

AlfredHealth

Questions

Tash Jennings
0409437097
N.Jennings@alfred.org.au

Or
Dr Gerard Oreilly
0438338414

Australian Government
National Health and Medical Research Council
NHMRC

Clinical research assistant duties. 1000- 1900

Housework

1. introduce yourself to resource nurse at main desk

2. grab all equipment out of red box in fast track office.

3. ensure you have pens for consent clip boards

4. introduce yourself to NP and registrar working in fast track and remind them the trial is happening during this shift. Introduce yourself to RN in fast track and remind them about documenting PS

5. make sure you have at least 20 consent forms ready to go. They are numbered so try and go in order.

6. put up trial signs on computer at triage and fast track

Trial work

8. watch screen and identify patients satisfying criteria

9. hand out PICF and explain they are invited to read and participate in the trial. Get 4 UR stickers from each eligible patient. Put 1 UR sticker on the eligibility log form for every patient you hand a PICF to. We need to keep count of how many refuse to participate or turn out to be ineligible.

10. collect the signed consent form, place 1 UR sticker on it and pick the next numbered envelope. Envelopes are ordered numerically. Please take the next number envelope in order. Inside the envelope will be the card determining what intervention the patient has been randomised to. i.e. Standard or NP care and a baseline data collection form

11. place 1 UR sticker on baseline data collection form and complete the patient information. Then staple the randomisation card to it.

12. place a pink sticker for NP care or green sticker for standard care on patients red folder

13. place the intervention code ie. NP or standard on disposition/plan field on computer screen

14. photocopy consent form and return a copy to the patient

15. place the completed baseline data collection form with stapled card in the red envelope in the red research box. Then place the last UR sticker from that patient on the data collection outcomes form.

16. TEXT number of patients at end of shift to 0409437 097.

Appendix F: RCT Participant Information and Consent Form

Participant Information and Consent Form: Patient version

Alfred Hospital Emergency and Trauma Centre

Full Project Title:

A pragmatic randomized control trial evaluating emergency nurse practitioner service.

Principle Researcher: Mrs Natasha Jennings

Associate Researchers: Gerard O'Reilly, Glenn Gardner

Please read this information sheet carefully and ask questions about any aspect that you don't understand.

Emergency Departments have seen a large growth in patient presentations over the last 5 years. With larger numbers seeking care in emergency departments, many hospitals have introduced different care providers to cope with this demand. Nurse practitioners are new care providers introduced in this hospital.

We are conducting a research study to compare the effectiveness of NURSE PRACTITIONERS on service and quality of patient care outcomes, with that of standard care in the ED.

Nurse Practitioners have been working in the Alfred Emergency and Trauma Centre since 2004. Their expanded nursing role allows them to manage the care of patients independently without the need to see a doctor. You may present to the emergency department with a painful arm and the nurse practitioner will assess, prescribe you pain killers, order and review your x-ray and manage your condition and arrange your discharge.

Patients often treated by Nurse Practitioners include those presenting with pain. You are invited to be a participant in the study as you have presented today with an injury and you

are suffering pain. This participant information and consent form outlines the details of the research project and what is involved if you decide to take part.

Participation is voluntary and you may withdraw at any stage during your stay in the Emergency Department.

Your care and waiting time within the Emergency Department will not be affected by your involvement in the research study.

If you decide to take part, you will be asked to sign a consent form. By signing the form you are telling us that you;

- Understand what you have read;
- Consent to take part in the research project;
- Consent to be involved in the procedures prescribed;
- Consent to the use of your personal and health information as described;

You will be given a copy of this Participant Information and Consent form to keep.

1. What is the purpose of the research project?

The purpose of the research is to evaluate the effectiveness of nurse practitioners on service and quality of care outcomes in patients presenting to the emergency department with Pain.

The project will provide a much needed evidence base on the effectiveness of the NURSE PRACTITIONER service in Australian emergency departments. Specifically the study outcomes will provide

- Evidence on the relative effectiveness of nurse practitioner service on patient pain scores and time to analgesia
- Evidence on the influence of nurse practitioner service on specific emergency department service indicators of waiting time to assessment, numbers of patients who did not wait for treatment, overall length of stay in the emergency department and unplanned presentations.
-

The results of this project will be used by the researcher (Natasha Jennings) to obtain a Doctor of Philosophy degree, undertaken at the Queensland University of Technology.

The researcher has been funded by the National Health and Medical Research Council on a Dora Lush post graduate scholarship to undertake the project.

2. What does participation in this research study involve?

There are several criteria that you must fulfil to be considered as a participant in this study, these include;

- Over 16 years age
- Assigned for management in the fasttrack zone
- Able to give informed consent
-

Your details will be obtained from the triage nurse. You will be given this patient information sheet and the details of the study will be explained to you by the Clinical Research assistant

on duty. If you decide to proceed you will be asked to sign the attached consent form and return it to the Clinical research assistant.

Your care and treatment will follow the usual trend for patients presenting with fast track zone complaints. That is, you may be seen and treated by a senior Doctor OR a Nurse Practitioner

RESEARCH PROCEDURES:

As a study participant you will be examined by the staff involved in the study, that is, either a Nurse Practitioner or Doctor. The following questions will be asked;

- What is your presenting complaint?
- Your past medical and social history and
- Where is the pain? And how would you rate it on a numeric scale?

The Nurse Practitioner OR the Doctor will make a decision on your diagnosis, treatment and complete your emergency management. All your information will be entered on your patient health record and be de-identified and used in data collection.

There are no costs associated with participating in this research project, nor will you be paid.

3. What are the possible benefits?

There will be no direct benefits from participating in the research. The possible benefit will be that you are participating in everyday real life research to evaluate service and quality of patient care for emergency patients. Being a participant enables you to make a difference in changing emergency department practices to benefits all patients.

4. What are the possible risks?

You may be stressed and in pain and therefore not want to be asked more questions from the clinical research assistant and treating Doctor/ Nurse Practitioner. You will be offered pain relief early in your care to treat the pain.

5. Do I have to take part in this research project?

Your participation in this research project is voluntary. If you decide not to take part your care will not be altered in any way. You may withdraw your participation at any time during your stay in the emergency department without affecting your care.

6. How will I be informed of the final results of this research project?

The final results will be available via the Alfred Website; http://www.alfred.org.au/enp/. A link will connect to relevant publications and results. Alternatively participants can contact Natasha Jennings directly who will make the results available on an individual basis.

7. What will happen to information about me?

Information collected for the study will be outlined on a standardised data collection form. The only identifying feature on this form is your hospital number. Your name and date of birth will not appear on the form. The treating clinician will document the history, examination and management of your injury in your hospital file as per usual processes.

Any publication or presentation will only identify patients and staff as groups and therefore your individual identity will not be revealed.

8. Can I access research information kept about me?

In accordance with relevant Australian and Victorian legislation you have the right to access the information collected and stored by researchers.

Please contact one of the nurse practitioner researchers if you would like to access your information.

In accordance with regulatory guidelines, the information stored will be kept for 7 years and then destroyed.

9. Is this research project approved?

This research project has been approved by the Alfred Human Research and Ethics Committee and the Queensland University of Technology Human Research and Ethics committee.

The project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

10. Consent

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project.

I understand that I will be given a signed copy of this document to keep.

Participant's Name (printed) ……..

Signature …….. Date ……..

Declaration by researcher; I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researchers Name (printed) ……

Signature …… Date ……

Note: All parties signing the consent section must date their own signature.

11.Who can I contact?

If you have any queries regarding your involvement in this research project, please contact the principle researcher;

Name: **Natasha Jennings**

Position: Nurse Practitioner Emergency and Trauma Centre

Ph: (03) 9076 3405

If you have any complaints about any aspect of the project, the way it is being conducted or any general queries about being a research participant, please contact;

Name: Ms Emily Bingle

Position: Research Governance Officer, The Alfred Hospital

Ph: (03) 9076 3619

Name: Ms Ashley Steele

Position: Research Governance Officer, Queensland University of Technology

Ph: (07) 3138 2091

Appendix G: RCT Ethics Approval QUT and Alfred HREC

TheAlfred

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 506/13

Project Title: A randomised control trial evaluating outcomes of emergency nurse practitioner service.

Principal Researcher: Ms Natasha Jennings

Project Proposal Version 3 **dated:** 20-Nov-2013

Participant Information and Consent Form Version 7 **dated:** 20-Nov-2013

*was considered by the Ethics Committee on **28-Nov-2013**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **10-Dec-2013***

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report on the anniversary of approval and on completion of the project *(forms to be provided)*;

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

SPECIAL CONDITIONS

None

SIGNED:

R Frew
Secretary, Ethics Committee

Project Title: A randomised control trial evaluating outcomes of emergency nurse practitioner service.

Ethics category: Human - Administrative Review

QUT approval number: 1300000838 (As per The Alfred Human Research and Ethics Committee,The Alfred Hospital, 55 Commercial Road, Melbourne, Victoria 3004, Australia

ABN 27 318 956 319, Approval number: Project No: 506/13)

QUT clearance until: 10/12/2014

We are pleased to advise that your application has been reviewed and administratively approved by the Chair, University Human Research Ethics Committee (UHREC) based on the approval gained from the responsible Human Research Ethics Committee (HREC). We note this HREC has awarded the project ethical clearance until 10/12/2014.

CONDITIONS OF APPROVAL

Please ensure you and all other team members read through and understand all UHREC conditions of approval prior to commencing any data collection:

- Standard: Please see attached or www.research.qut.edu.au/ethics/humans/stdconditions.jsp
- Specific: None apply

Projects approved through an external organisation may be subject to that organisation's review arrangements. Researchers must immediately notify the QUT Research Ethics Unit if their project is selected for investigation / review by an external organisation.

VARIATIONS

All variations must first be approved by the responsible HREC before submission to QUT for ratification. Once approval has been obtained please submit this to QUT using our online variation form:

www.research.qut.edu.au/ethics/humans/var/

MONITORING

Please ensure you also provide QUT with a copy of each adverse event report and progress report submitted to the responsible HREC.

Administrative review decisions are subject to ratification at the next available UHREC meeting. You will only be contacted again in relation to this matter if UHREC raises additional questions or concerns.

Please don't hesitate to contact us if you have any queries.

We wish you all the best with your research.

Kind regards

Janette Lamb on behalf of the Chair UHREC

Research Ethics Unit | Office of Research | Level 4 88 Musk Avenue

Kelvin Grove | Queensland University of Technology

p: +61 7 3138 5123 | e: ethicscontact@qut.edu.au | w:

www.research.qut.edu.au/ethics/

Appendix H: RCT Data Collection Tools

E-NP RCT Data Collection Form - Baseline

Place UR sticker here	**Date:**

Time of presentation __:__

Please circle the correct response

Mode of transport	**Private**		**AV**				**Other**			
Analgesic taken at home	**Yes**				**No**					
Type of analgesic and name _____ **If more than 1 analgesic name**	**Simple**	**NSAID**	**OPOID**	**Other**	**Unknown**					
Dose	_____ **Unit**									
Time taken	__:__									
Pain Score (0)	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Consent	**Yes**				**No**					
Randomisation group	**Standard**				**Intervention**					

Other

E-NP RCT Data Collection Form - Outcomes

Place UR sticker here	Date

Please enter or circle the correct response

Was analgesia given between presentation and time seen by treating clinician	Yes	No

Type of analgesic Time: __:__	Simple	NSAID	OPOID	Other

Time seen by treating clinician:	__:__

Pain score (1) Time: __:__	0	1	2	3	4	5	6	7	8	9	10	Other

Type of analgesic Time: __:__	Simple	NSAID	OPOID	Other

Pain Score (2) Time: __:__	0	1	2	3	4	5	6	7	8	9	10	Other

Type of analgesic Time: __:__	Simple	NSAID	OPIOD	Other

Pain Score (3) Time: __:__	0	1	2	3	4	5	6	7	8	9	10	Other

Type of analgesic	Simple	NSAID	OPOID	Other

Time: __:__				
Pain Scores > (3)	**Yes**	**No**	**Time: __:__**	

Reference to EBG	**Yes**	**No**	
Time of discharge:	**__:__**		
Did they wait?	**Yes**	**No**	
Did they represent? Date __/__/__	**Yes**	**No**	**Time: __:__**

Data spreadsheet

Most statistical software packages are usually spreadsheet based and it was decided to use a spreadsheet we could easily export into our nominated software package. The data was stored in Microsoft Excel and data for each patient was entered into each row of the spreadsheet horizontally. Each patient's individual responses are coded in one cell of the spreadsheet and all responses from the sample taken line up under the appropriate column. The columns of the spreadsheet correspond to the outcomes collected at both baseline and outcomes.

Our data collection forms were designed to allow for responses to be easily coded into a suitable format for easy data entry and statistical analysis. The coding manual converted the text responses into numeral codes and a coding manual produced for verification and transparency. Our coding manual described each variable and derived codes for all responses, allowing for complete data analysis. The following steps were utilised in our coding manual

1. Variable names and labels defined

i.e. ID - unique identifier only- no scale required, as no sub analysis except to check for any duplications

2. Range of expected responses detailed

i.e. Sex - Male = 0, Female = 1, Missing = -1

3. Numerical values for categorical data detailed

i.e. Age – Valid range 16-120, Missing = -1

4. Instructions for missing data determined

i.e. Missing = -1

5. Identifying the measurement types for each variable

i.e. ID – Scale, sex– nominal, Pain scale – ordinal

RCT Coding Manual

VARIABLE NAME	DESCRIPTION OF VARIABLE	DATA CODING
Baseline data		
patientur	unique participant identifier	(integer)
age	age of participant in years	continous 16-90
date	date of presentation	date
time	time of presentation	mm:hh
ats	ATS catergory	ordinal 2-5
triagedes	triage nurse description on firstnet	free script
modeoftrans	how they arrived at hospital	0 = private; 1= AV, 2 = other
analgeathome	did they have analgesia at home	1 = yes; 0 = no
typeofanalg	what analgesia did they have	1 = simple analgesic 2= nsaid, 3 = opiod, 4 = other, 5 = unknown
nameofanalg	what was the name of the drug	free script
dose	what dose of analgesia did they have	Unit

timeofprehospanalg	what time did they have analgesia at home	mm:hh
ps0	pain score on arrival by triage nurse	1-10 on VNPS
groupalloc	standard or NP care	1 = Standard, 0 = NP
Outcomes data		
analpreclinic	was analgesia given between presentation and time seen by treating clinician ie. At traige or in FT	1 = yes; 0 = no
typeofanalg	what analgesia did they have	1 = simple analgesic 2= nsaid, 3 = opiod, 4 = other, 5 = unknown
timeofanalpreclinic	what time did they have this analgesia prior to seeing treating clinician	mm:hh
wtmins	waiting time from initial presentation to being seen by treating clinician	mm:hh
ps1	pain score on initial assessment by treating clinician	1-10 on VNPS
ps1time	time of pain score 1	mm:hh
analg1	type of first analgesia	1 = simple analgesic 2= nsaid, 3 = opiod, 4 = other, 5 = unknown
analg1time	time of first analgesia	mm:hh
ps2	pain score 30 minutes post first analgesia	1-10 on VNPS
ps2time	time of pain score 2	mm:hh
analg2	type of second analgesia	1 = simple analgesic 2=

		nsaid, 3 = opiod, 4 = other, 5 = unknown
analg2time	time of second analgesia	mm:hh
ps3	pain score at discharge	1-10 on VNPS
ps3time	time of pain score 3	mm:hh
analg3	type of third analgesia	1 = simple analgesic 2= nsaid, 3 = opiod, 4 = other, 5 = unknown
analg3time	time of third analgesia	mm:hh
ps>3	were more than 3 pain scores recorded	1 = yes; 0 = no
ebg	were there mention of clinical rules in clinician notes- ottawa knee, ottawa ankle and burns intranet	1 = yes; 0 = no; 2 = ankle; 3 = knee; 4 = burns
losmins	length of stay until discharged from firstnet	(numeric with one decimal place)
dnw	number of patients who did not wat to compete their treatment	
repres	patients whom represent within 48 hours in regards to initial presentation	1 = yes; 0 = no
daterepres	date they represented	date
timerepres	time they represented	mm:hh